

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Clean Chemistry, Inc.,
Petitioner,

v.

Enviro Tech Chemical Services, Inc.,
Patent Owner

IPR2025-01471
U.S. Patent No. 9,363,997

DECLARATION OF ALEXANDER M. KLIBANOV, PH.D.

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Claims of the '997 Patent

1. A method of generating a non-equilibrium solution of peracetic acid, comprising:
 - a. providing water;
 - b. introducing triacetin and aqueous hydrogen peroxide to the water;
 - c. mixing the triacetin and the aqueous hydrogen peroxide with the water to form a mixture;
 - d. adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture; and
 - e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.
2. The method of claim 1, wherein the triacetin and the aqueous hydrogen peroxide are introduced simultaneously
3. The method of claim 1, wherein the triacetin and the aqueous hydrogen peroxide are introduced sequentially with either one first.
4. The method of claim 1, wherein the provided water is an aqueous stream.
5. The method of claim 1, wherein the provided water is contained in a mixing tank or other vessel.
6. The method of claim 1, wherein the aqueous source of the alkali metal or earth alkali metal hydroxide is sodium hydroxide.
7. The method of claim 6, wherein the sodium hydroxide is about 1.82% to about 7.28%.
8. The method of claim 1, wherein step (d) is performed simultaneously with step (b).
9. The method of claim 1, further comprising allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid.

10. The method of claim 9, wherein the time to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid is about 30 seconds to about five minutes.

11. The method of claim 10, wherein the percent of triacetin that is converted into peracetic acid is about 40.9% to about 85.7%.

12. The method of claim 6, wherein the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is about 4.2:3.8:1.

13. The method of claim 1, wherein steps (a) through (e) are performed on a continuous basis.

14. The method of claim 1, wherein steps (a) through (e) are performed on an intermittent basis.

I. INTRODUCTION

I, Dr. Alexander M. Klibanov, declare as follows:

1. I have been retained by counsel for Petitioner, Clean Chemistry, Inc. (“Clean Chemistry” or “Petitioner”), as a technical expert in connection with the proceeding identified above. I submit this Declaration in support of Clean Chemistry’s Petition for *Inter Partes* Review (“IPR”) of United States Patent No. 9,363,997 B2 (“the ’997 patent”).

2. I am being compensated at my customary hourly consulting rate for my time spent working on this matter. I have no personal or financial stake or interest in the outcome of the present proceeding.

II. BACKGROUND AND QUALIFICATIONS

3. My *Curriculum Vitae*, attached as EX1004, summarizes my education and academic experience. Among other things, it lists all my professional publications and issued U.S. patents.

4. I am currently a Professor Emeritus of Chemistry and Bioengineering at the Massachusetts Institute of Technology (“M.I.T.”), where I taught and conducted research for over 40 years. From 2014 to 2019 (and also from 2007 to 2012), I held the Novartis Endowed Chair Professorship at M.I.T. From 2012 to 2014, I held the Roger and Georges Firmenich Endowed Chair Professorship in Chemistry. Prior to that, I was a Professor of Chemistry and a Professor of

Bioengineering at M.I.T., positions I held from 1988 and 2000, respectively. From 1979 to 1988, I was an Assistant Professor, then an Associate Professor, and thereafter a Full Professor of Applied Biochemistry in the Department of Applied Biological Sciences (formerly the Department of Nutrition and Food Science) at M.I.T.

5. I obtained my M.S. degree in Chemistry from Moscow University in Russia in 1971 and Ph.D. in Chemical Enzymology (a branch of medicinal chemistry) from the same University in 1974. Thereafter, I was a Research Chemist at Moscow University's Department of Chemistry for three years. From 1977 to 1979, following my immigration to the United States, I was a Post-Doctoral Associate at the Department of Chemistry, University of California in San Diego.

6. Over the last 50+ years as a practicing chemist, I have extensively researched, published, taught, and lectured in many areas of chemistry, including biological, protein, medicinal, and formulation chemistry.

7. During my 40 years as a M.I.T. professor, I taught numerous undergraduate and graduate courses in various areas of chemistry, including general, organic, physical, and biological chemistry.

8. I have earned numerous prestigious professional awards and honors. For example, I was elected to the U.S. National Academy of Sciences (considered among the highest honors that can be given to an American scientist) and also to the

U.S. National Academy of Engineering (considered among the highest honors that can be given to an American engineer). I am also a Founding Fellow of the American Institute for Medical and Biological Engineering and a Corresponding Fellow of the Royal Society of Edinburgh (Scotland's National Academy of Science and Letters). In addition, I have received the Arthur C. Cope Scholar Award, the Marvin J. Johnson Award, the Ipatieff Prize, and the Leo Friend Award, all from the American Chemical Society, as well as the International Enzyme Engineering Prize.

9. I currently serve on the Editorial Boards of over a dozen scientific journals, including "Open Journal of Pharmacology," "Applied Biochemistry and Biotechnology," "Nanocarriers," "Open Access Academic Books in Chemistry," "Biotechnology and Bioengineering," "Journal of Biological Chemistry and Molecular Pharmacology," "Recent Patents in Biotechnology," "Archives of Medical Biotechnology," "Current Pharmaceutical Biotechnology," and "International Journal of Drug Design, Delivery, and Safety."

10. I have published over 315 scientific papers in various areas of chemistry. I am a named inventor of 33 issued United States patents and of a number of pending ones. I have given over 370 invited lectures, including many distinguished named lectureships, at professional conferences, universities, and corporations all over the world, many dealing with formulation, stability, stabilization, and biological evaluation of pharmaceutically active proteins.

According to a recent Stanford University-led study, the overall impact of my published work places me in the top 0.01% of all scientists in the world.

11. In addition to my research and teaching activities at M.I.T., I have consulted widely for pharmaceutical, medical device, and biotechnology companies. Those consulting relationships have included both innovator and generic pharmaceutical companies.

12. I also have founded seven start-up industrial companies and have been on the scientific advisory boards and/or boards of directors of those companies and of many others.

13. I am familiar with synthetic methods, production, and uses of peracetic acid (“PAA”), particularly in connection with my long-term consultant relationship with E. I. du Pont de Nemours and Company (DuPont) that began in the early 1990s. As part of my consulting work for DuPont, I worked on a project related to industrial processes for synthesizing PAA. While my work on this project focused on the use of perhydrolase enzymes for PAA synthesis, I also became knowledgeable about non-enzymatic PAA synthetic methods.

14. My opinions and views set forth in this declaration are based on my education, training, and professional experience, as well as on the materials I have reviewed (see the next paragraph) in preparing this declaration and on the state of scientific knowledge in the art pertaining to the subject matter of the '997 patent at

the time of its earliest priority date of March 24, 2011.

III. MATERIALS REVIEWED AND CONSIDERED

15. In forming my opinions expressed herein, I have reviewed the following materials:

Ex. No.	Description
1001	U.S. Patent No. 9,363,997 (“’997 patent”)
1002	Prosecution History of U.S. Patent No. 9,363,997
1005	JP 2006-045147 A (“Okano”) (Translated)
1006	WO 2001/046519 (“Withenshaw”)
1007	U.S. Patent No. 3,432,546 (“Oringer”)
1008	U.S. Patent No. 7,271,137 (“Tucker”)
1009	U.S. Patent No. 2,448,252 to Cornthwaite et al. (“Cornthwaite”)
1010	U.S. Patent Application Publication No. US 2009/0043123 to Copenhafer et al. (“Copenhafer”)
1011	U.S. Patent Application Publication No. US 2009/0175956 to Buschmann et al. (“Buschmann ’956”)
1012	Luyben, Chemical Reactor Design and Control (2007) (“Luyben”)
1013	Hill, Chemical Engineering Kinetics & Reactor Design (1977) (“Hill”)

IV. LEGAL PRINCIPLES

16. I am not a lawyer or patent scholar, but I have been informed of certain legal principles that are relevant to my analysis presented herein by Clean Chemistry's counsel ("counsel"). My understanding of these legal principles explained to me by counsel is outlined below in this section of the present Declaration.

A. A Person of Ordinary Skill in the Art

17. United States patents and their prior art should be evaluated from the perspective of a hypothetical person of ordinary skill in the art at the time of the invention (a "POSA").

18. A POSA is a competent person of ordinary creativity. He or she is presumed to be familiar with all publicly available relevant prior art at the time of the invention of the patent in question (here, the '997 patent).

19. In my opinion, a POSA with respect to the subject matter of the '997 patent would have had at least a bachelor's degree in chemistry, chemical engineering, or a related discipline, plus a couple of years of practical experience in chemical syntheses or equivalent knowledge and work experience. I consider myself at least a POSA under this definition.

20. I have considered the issues, and arrived at my conclusions described

in this Declaration, from the perspective of such a POSA.

B. Claim Construction

21. Claims of a patent, and terms included in those claims, should be interpreted from the perspective of a POSA at the time of the invention (March 24, 2011, in the case of the '997 patent).

22. A patent's claims, its specification, and the file history (collectively referred to as "intrinsic evidence") should be analyzed to arrive at the proper interpretation of a claim term.

23. Sometimes (as in the case of the '997 patent), a patentee can include a particular definition of a claim term in the patent specification. In such instances, the claim term generally should be interpreted according to that definition provided in the patent specification.

24. The patent claim should be interpreted in light of the intrinsic evidence, which includes the language of the claim in question and of the other claims in the patent, as well as the specification of the patent and the relevant prosecution history of the patent. Other evidence, which is considered extrinsic evidence and not in the written record of the patent or its prosecution history, such as relevant technical dictionaries and learned treatises, also may be considered if it is consistent with the intrinsic evidence. However, if the meaning of the claim is clear from the intrinsic

evidence, then there is no reason for a POSA to look into extrinsic evidence.

C. Obviousness

25. Relevant factual considerations for an obviousness analysis include (1) the scope and content of the prior art; (2) differences between the prior art and the patent claims; and (3) the level of skill possessed by a hypothetical person of ordinary skill in the art at the time of the invention.

26. Obviousness analysis of a patent claim can be based on either a single prior art reference or a combination of two or more of such references that disclose all of the features of the claim, whether expressly or inherently.

27. If a prior art reference discloses fewer than all limitations of a patent claim, the claim may still be obvious if the differences between its subject matter and the prior art reference would have been obvious to a POSA at the time of the invention.

28. Also, a patent claim that recites a specific range of values of a variable can be rendered obvious by prior art that teaches a range that encompasses, or overlaps with, the recited range of values, unless the recited range demonstrates some criticality, such as unexpectedly superior results.

29. A patent claim that recites a combination of known elements combined according to known methods that produces predictable results is probably obvious.

30. However, an obviousness determination of a patent claim should not be based on the benefit of hindsight gained by a POSA from the disclosure of the patent under consideration.

V. SUMMARY OF CONCLUSIONS

31. Based on my professional knowledge and experience, as well as on my review of the intrinsic evidence and of the prior art as of the constructive time of the invention (March 24, 2011), I have concluded that claims 1 through 14 of the '997 patent are obvious over at least the prior art cited in this IPR Declaration.

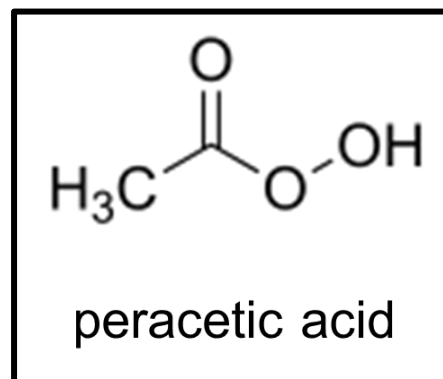
VI. TECHNOLOGY BACKGROUND

A. Overview of the Technology

32. In this section, I provide an overview of knowledge that a POSA would have possessed based on the scope and content of the relevant prior art as of March 2011.

1. Peracetic acid (PAA)

33. Peracetic acid (CH_3COOOH or $\text{CH}_3\text{-C(=O)-O-OH}$, often abbreviated as PAA and also referred to as peroxyacetic acid) has been well known as a disinfectant and sanitizing agent. (See, e.g., EX1001 ('997 patent), 1:22-33 (Field of Invention); EX1008 (Tucker), 1:55-2:19; EX1009 (Cornthwaite), 1:1-7.) When in



an alkaline aqueous environment, PAA is mostly in a dissociated form, namely as a peracetate anion. (See, e.g., EX1010 (Copenhafer), [0057] (“In alkaline reaction conditions, e.g., above a pH value of about 8, it should be noted that the peracetic acid reaction product will be substantially in the dissociated form, a peracetic acid salt form or peracetate form.”).)

34. PAA possesses strong oxidation capabilities for functioning as a sterilizing/disinfectant or bleaching agent, and it has been utilized as such, for example, in hospitals, food production plants, water treatment, and papermaking. (EX1001 ('997 patent), 1:22-33 (“Peroxyacetic acid disinfectants are also used in the treatment of cooling water, process water, and municipal wastewater. Other uses include slime and biofilm removal in papermaking processes.”); see also, e.g., EX1009 (Cornthwaite), 1:34-35 (PAA as a bleaching agent); EX1005 (Okano), [0002] (in “food production plants, pharmaceutical production plants, hospitals, nursing homes, kitchens, bathrooms, and the like”); EX1010 (Copenhafer), [0003] (PAA “is a well known chemical for its strong oxidizing potential”), [0005] (“Aqueous solutions of peracetic acid, at dilute concentrations below 5 wt % peracetic acid, are widely used in a variety of end use applications for their wide spectrum antimicrobial and biocidal properties, as a bactericide, fungicide, disinfectant and sterilant, and also for their bleaching properties.”); EX1008 (Tucker), Abstract (“Examples of suitable applications include disinfection of food

processing equipment, disinfection of areas containing livestock, mold remediation, sterilization of medical instruments and direct disinfection of food surfaces, such as beef carcasses.”.)

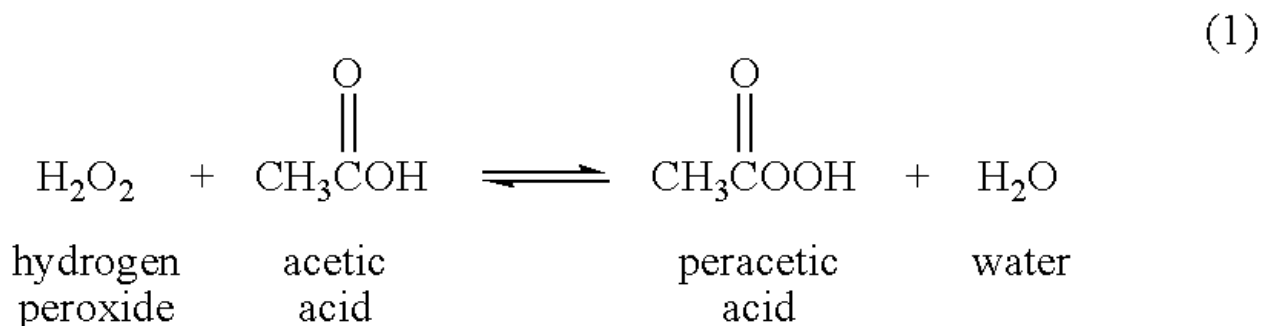
35. It has long been well-known that organic peracids, including peracetic acid in particular, can be chemically generated by reacting a compound containing an acetyl group with a nucleophilic oxidizing compound, such as the strongly nucleophilic hydroperoxy anion (OOH^-), according to the following generalized reaction scheme (where $\text{R} = \text{CH}_3$ for PAA and “L” stands for a so-called leaving group, such as “OH”):



(EX1008 (Tucker), 5:35-42, 5:51-64, 6:39-62; *see also, e.g.*, EX1009 (Cornthwaite), 1:1-29; EX1005 (Okano), [0008] (“The present invention relates to a sterilizing cleaner composition for hard surfaces, containing water and an organic peracid obtained by reacting (A) an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group ... and (B1) hydrogen peroxide ...”), [0015]; EX1011 (Buschmann ’956), [0005], [0027].)

36. Acetyl precursors taught in the prior art for generating PAA include acetic acid, tetraacetyl ethylene diamine (TAED), monoacetin (glycerol monoacetate), diacetin (glycerol diacetate), and triacetin (glycerol triacetate). (EX1008 (Tucker), 6:52-53, 7:6-14 (identifying “glycerol acetate (monoacetin), glycerol diacetate (diacetin), glycerol triacetate (triacetin)”); EX1005 (Okano), [0008], [0015]; EX1011 (Buschmann ’956), [0027].) Hydrogen peroxide is often the preferred oxidant. (EX1008 (Tucker), 5:51-53; EX1005 (Okano), [0008]; EX1009 (Cornthwaite), 2:46-50; EX1011 (Buschmann ’956), [0027].) Suitable bases include inorganic bases such as sodium hydroxide. (EX1008 (Tucker), 5:35-42, 6:17-38; *see also* EX1005 (Okano), [0039], [0057].)

37. A POSA would have known that equilibrium solutions of peracetic acid can be generated in an aqueous solution with an acetyl source, such as acetic acid, and hydrogen peroxide (H₂O₂ or HO-OH), under acidic conditions:



(EX1011 (Buschmann ’956), [0004]-[0005] (“‘Equilibrium PAA’ is most commonly produced by mixing hydrogen peroxide, acetic acid, water and an acid catalyst.”);

EX1010 (Copenhafer), [0006] (“Peracetic acid is commonly manufactured by reaction of acetic acid and concentrated hydrogen peroxide, with an acid catalyst, *e.g.*, sulfuric acid, in a continuous process that is allowed to proceed for days in order to achieve high reaction yields.”).)

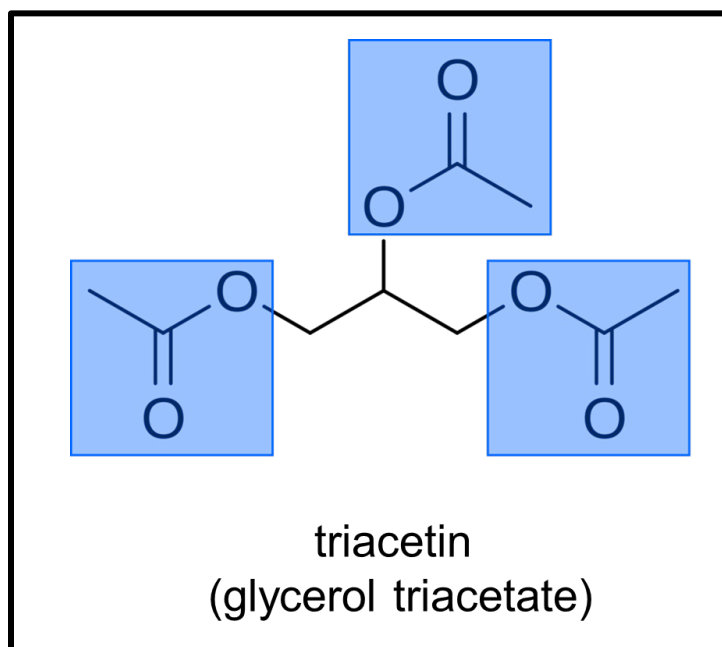
38. A POSA would also have known that non-equilibrium solutions of peracetic acid can be generated using an acetyl precursor, hydrogen peroxide, and water under alkaline conditions. (EX1011 (Buschmann '956), [0027] (“non-equilibrium PAA is produced by reacting a properly chosen acyl donor with hydrogen peroxide under alkaline conditions (pH greater than about 10) to produce non-equilibrium peroxy carboxylic acid.”); EX1005 (Okano), [0008] (“obtained by reacting (A) an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group that may have a hydroxyl group (herein referred to as component (A)) and (B1) hydrogen peroxide (herein referred to as component (B1)) in water ... and *at a pH of 8 to 12...*”), [0048] (“[t]he component (A) and the component (B1) *react under alkaline conditions ... in water to generate an organic peroxy acid*”) (emphases added).)

39. Non-equilibrium peracetic acid aqueous solutions obtained under alkaline conditions have certain advantages over equilibrium solutions since they require less excess starting material and because hydrogen peroxide therein is

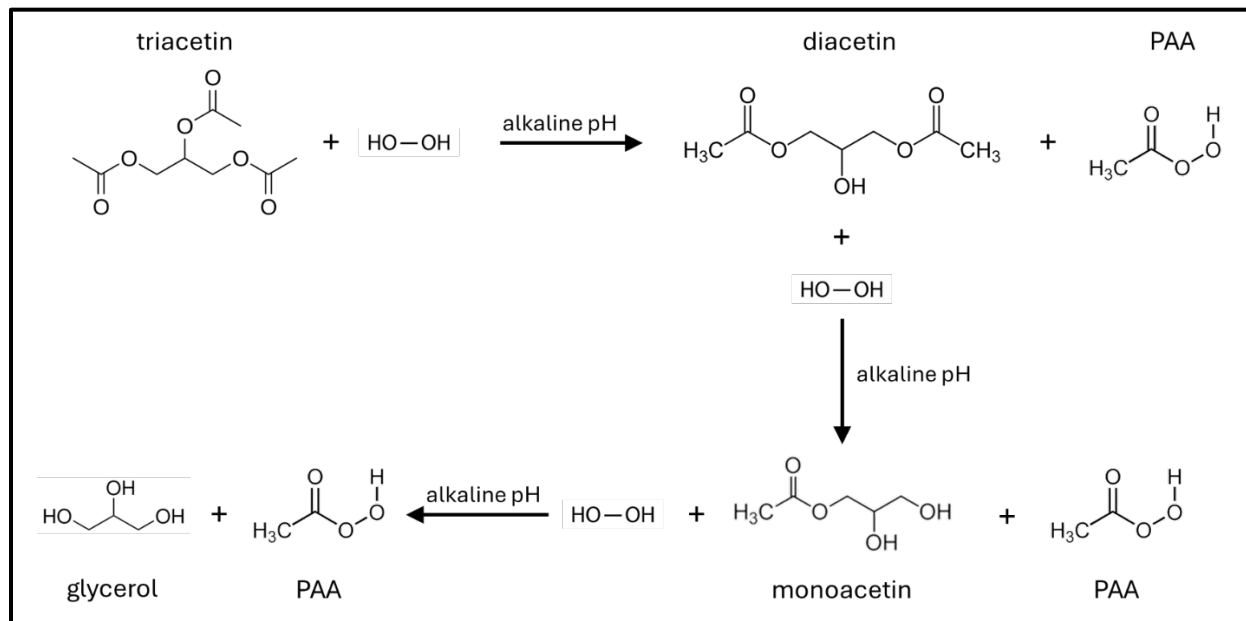
primarily in the form of strongly nucleophilic hydroperoxy anions (OOH^-). (See EX1008 (Tucker), 6:39-49; EX1011 (Buschmann '956), [0012], [0028].) In particular, a POSA would have known that non-equilibrium PAA solutions could be generated “by reacting an ester of a carboxylic acid [*e.g.*, acetic acid] with an ***alkaline*** aqueous peroxide solution,” which reaction is rapid and involves relatively inexpensive starting materials. (EX1009 (Cornthwaite), 1:34-51 (emphasis added); 2:29-33 (“in order to carry out the reaction between the ester and the peroxide, a highly alkaline condition is requisite”).) Accordingly, a POSA would have known that the reaction to form PAA from an ester of acetic acid and hydrogen peroxide is a base-catalyzed non-equilibrium reaction. (*E.g.*, EX1009 (Cornthwaite), 1:1-29, 2:41-3:8; EX1008 (Tucker), 5:35-42, 6:17-38; EX1005 (Okano), [0039] (peroxyacid is “prepared by setting the pH to 8 to 12, preferably 9 to 11 (first step)”), [0048] (“The component (A) and component (B1) react under alkaline conditions ... in water to generate an organic peroxy acid, and therefore, a component that gives such a pH may be used as the component (C). Specifically, examples include alkali metal hydroxides such as sodium hydroxide....”); EX1011 (Buschmann '956), [0027].)

40. Triacetin, also known as glycerol triacetate, was a well-known and preferred liquid acetyl precursor for reacting with hydrogen peroxide under alkaline conditions to generate non-equilibrium PAA solutions. (See EX1005 (Okano), [0014]; *see also* EX1008 (Tucker), 7:12, 8:16.) A POSA would have recognized

that triacetin is a triester of glycerol and acetic acid having three acetyl groups in the form of three carboxylic acid ester groups (shown in blue boxes below):



41. Under alkaline conditions, the carboxylic acid esters of triacetin react with hydrogen peroxide to generate a non-equilibrium solution of PAA according to the following step-wise generation of three mole-equivalents of PAA in the triacetin → diacetin → monoacetin → glycerol sequential conversion (assuming that hydrogen peroxide is not a limiting reagent):



2. Methods for generating PAA

42. It has long been known that PAA can be generated in an aqueous reaction of an acetyl precursor with hydrogen peroxide under alkaline conditions in a variety of chemical manufacturing processes, including batch and continuous processes employing standard batch vessels, continuous stirred tank reactor, and/or tubular reactor. (See, e.g., EX1012 (Luyben), xiv (“The three *classical* generic chemical reactors are the batch reactor, the continuous stirred-tank reactor (CSTR), and the plug flow tubular reactor (PFR).”), 19 (“the *classical* types of reactors: batch, continuous stirred-tank reactor (CSTR), and plug flow reactor (PFR)” (emphasis added)); see also EX1012 (Luyben), 19-24 (CSTR, batch reactor, and tubular reactor); EX1013 (Hill), 247-252.) As discussed further below, the prior art had disclosed a variety of exemplary methods for generating PAA aqueous solutions by

reacting an acetyl precursor with hydrogen peroxide under alkaline conditions employing standard chemical unit operations and reactor types.

a) *Known methods for batch generation of PAA*

43. Batch processes are commonly used for aqueous reactions, particularly when the relative amount of production is small. (See, e.g., EX1013 (Hill), 248.) In this regard, Okano discloses an exemplary, laboratory-scale batch production of about 1 liter of a sterilizing composition of PAA that involves adding and mixing an alkaline solution of sodium hydroxide into a solution containing the acetyl precursor triacetin, hydrogen peroxide, and water, as follows:

<Preparation of Sterilizing Cleaner Composition (I)>

(A) 50 g of triacetin (made by Cognis Japan, active ingredient 100%) and (B) 25 g of hydrogen peroxide (made by Ube Chemira, active ingredient 60%) were mixed with 850 g of ion exchanged water, 75 g of an alkaline aqueous solution containing 27% sodium hydroxide and 1.3% of organic phosphonic acid (product name: Dequest 2010, made by Solucia) was poured in, and this was then mixed and stirred for 5 minutes. Afterward, 75 g of a mixed acid solution containing 30% sulfuric acid and 6% phosphoric acid was immediately added to prepare the sterilizing cleaner composition (I) containing the organic peroxy

acid. The pH (25°C) of the composition (I) was about 2, and the hydrogen peroxide content was about 1500 ppm.

(EX1005 (Okano), [0056]-[0057].)

b) *Known methods for continuous generation of PAA*

44. Continuous manufacturing operations that combine and mix an acetyl precursor with hydrogen peroxide under alkaline conditions to generate PAA were also well known in the art. For instance, Withenshaw discloses a multi-step “Peroxyacid Delivery Process” for the continuous generation of a peroxyacid from hydrogen peroxide solution and a “bleach activator” (*i.e.*, an acetyl precursor), which may be used for pulp bleaching in papermaking. (*E.g.*, EX1006 (Withenshaw), Abstract.) As another example, Oringer discloses a method for the “Manufacture of Peracetic Acid” using a tubular reactor for continuously generating PAA by reacting an acetyl precursor and hydrogen peroxide “in the presence of an alkaline catalyst comprising continuously introducing the reactants into a tubular reaction zone[.]” (*See* EX1007 (Oringer), Abstract (1:11-21), 2:35-56.)

VII. OVERVIEW OF THE '997 PATENT

A. Summary of the '997 Patent

45. The '997 patent recites 14 claims, of which only claim 1 is independent and claims 2 through 14 depend, directly or indirectly, from claim 1. (EX1001 ('997 patent), claims 1-14.) The '997 patent describes and claims methods for generating

non-equilibrium solutions of peracetic acid (PAA). (*See, e.g.*, EX1001 ('997 patent), Abstract.) “These methods comprise introducing triacetin sad [sic] aqueous hydrogen peroxide to water, mixing, and *then* adding an aqueous source of an alkali metal or earth alkali metal hydroxide. Triacetin is converted rapidly and with a high conversion rate into peracetic acid.” (EX1001 ('997 patent), Abstract (emphasis added)), which is the method recited in independent claim 1 of the '997 patent.

46. Similarly, the specification discloses a method for generating PAA that tracks the claims of the '997 patent wherein: (a) “[w]ater is provided on the site having the point-of-use. The water may be a flowing aqueous stream or it may be contained in a mixing tank or other vessel” (EX1001 ('997 patent), 5:48-50); (b) “in another embodiment, the acetyl precursor and the aqueous hydrogen peroxide may be introduced to the water separately, either sequentially, with either on first, or simultaneously” (*Id.*, 5:61-64); (c) “[t]he hydrogen peroxide-acetyl precursor solution and the water are mixed to form a mixture” (*Id.*, 5:65-66); (d) “[a]n aqueous source of an alkali metal or earth alkali metal hydroxide, such as sodium hydroxide, is provided on the site having the point-of-use. The aqueous source of an alkali metal or earth alkali metal hydroxide is added to the mixture” (*Id.*, 5:66-6:3); (e) “[a] reaction medium comprising a non-equilibrium solution of peracetic acid is formed” (*Id.*, 6:8-9).

47. Examples 1 through 18 of the '997 patent describe the preparation of hydrogen peroxide-triacetin solutions (*i.e.*, in general, hydrogen peroxide-acetyl precursor solutions). The molar/mole ratios of hydrogen peroxide to the acetyl precursor triacetin, as well as the weight percent concentrations of hydrogen peroxide and triacetin in the solutions prepared in Examples 1-18, correspond to, or fall within, the corresponding ranges subsequently recited in several claims of the '997 patent. (EX1001 ('997 patent), 9:53-34:45.)

B. Summary of the Prosecution History of the '997 Patent

48. I have reviewed the file (or prosecution) history of the '997 patent.

49. The application for the '997 patent was filed on April 8, 2015, as U.S. Application No. 14/681,938 (the "'938 application"). (*See* EX1002, 1.) The application, as filed, included the 14 claims that issued in the '997 patent (without any changes). (*Compare* EX1002, 62-63 (claims 1-14) *with* EX1001 claims 1-14.)

50. I understand that Applicants never submitted an IDS (*i.e.*, Information Disclosure Statement) identifying relevant prior art to the patent office during prosecution of the '938 application that became the '997 patent. I further understand that the sole cited reference identified on the face of the '997 patent is applicant's own parent, U.S. Patent No. 8,546,449 (the "'449 patent"). (*See* EX1001, Page 1 (References Cited).)

51. On December 7, 2015, the Patent and Trademark Office Examiner (the “Examiner”) issued a double patenting rejection of the 14 pending claims under the ’449 patent. (EX1002, 88-93.) Applicants responded by filing a terminal disclaimer over the ’449 patent. (EX1002, 98-100, 126, 129-131.) The terminal disclaimer was eventually approved by the Examiner. (See EX1002, 150-152 (“Reasons for Allowance 3. Since the terminal disclaimer against Harvey et al. ’449 has been filed and approved in the Office, the rejection of claims 1-14 under the obviousness-type double patenting over Harvey et al. ’449 has been overcome in the amendment filed on 4/19/2016.”).)

52. The Notice of Allowability from the Examiner on April 29, 2016, stated that “Claims 1-14 are neither anticipated nor rendered obvious over the art of record, and are therefore allowable.” (EX1002, 151.) However, based upon my review, there was no “art of record” other than the ’449 patent used to support the double-patenting rejection by the Examiner since that is the only reference cited on the face of the ’997 patent. (See EX1002, 93 (“Notice of References Cited” only identifying a single reference: “US-8,546,449”).) Moreover, although the Examiner stated that “[a] suggestion for modification of a reference to obtain the instant methods of use has not been found,” there is no indication of any specific prior art references that were searched and reviewed by the Examiner despite the existence of voluminous prior art relating to the generation of peracetic acid and the Examiner’s “Search

History” showing “1966” and “1834” prior art “Hits.” (EX1002, 171.)

53. The '997 patent issued on June 14, 2016.

VIII. CLAIM CONSTRUCTION

54. From my review of the claims, specification, and file history of the '997 patent, it appears that the claim terms therein would have had either their plain and ordinary meaning well familiar to a POSA or those expressly provided in the patent specification (EX1001 ('997 patent), 7:42-51). In the following, I provide my opinion that the plain meaning of the claim language used to recite the steps of the method in claim 1 of the '997 patent must be performed in the recited order. However, I further understand from counsel that the parties (*i.e.*, Petitioner and Patent Owner) have submitted a variety of competing claim construction positions in the underlying district court patent proceedings. To the extent that the parties' disputes regarding the interpretation of the claims are relevant to my opinions in this Declaration that demonstrate how the prior art satisfies and renders obvious the claims of the '997 patent, I identify within the Grounds herein how I am applying the claim language even though I do not necessarily endorse or adopt such an interpretation as being the correct interpretation of the claims in my opinion.

A. The Claimed Method Requires that the Recited Steps Be Performed in Order

55. I understand from counsel that, in general, a method claim reciting steps

is interpreted such that the steps need not be performed in order unless a specific order has been expressly or implicitly claimed. I also understand from counsel that the steps must be performed in order if, as a matter of logic or grammar, the recited language of the steps requires the steps to be performed in a given manner in order to perform successive steps. In other words, I understand that when aspects of a claim are recited in a manner that requires antecedent basis (*i.e.*, the claim recites “a” or “a/an [element]” and then later recites “the [element]”), such language in a method claim can necessarily require a sequential order of the steps.

56. In my opinion, the plain language of claim 1 of the '997 patent recites a method that requires the method steps to be performed in the order listed. This is because the claimed method is recited with such terms that require antecedent basis to steps which both logically and grammatically must be performed in a given order.

57. In particular, claim 1 of the '997 patent requires (emphases and underlining added) a step “a. ***providing water***,” followed by step “b. introducing triacetin and aqueous hydrogen peroxide ***to the water***,” indicating that step “a” must be performed before step “b.” Similarly, step “b. introducing ***triacetin and aqueous hydrogen peroxide*** to the water” is followed by step “c. mixing ***the triacetin and the aqueous hydrogen peroxide*** with the water to form a mixture,” indicating that step “b” must be performed prior to step “c.” Finally, step “c. mixing the triacetin

and the aqueous hydrogen peroxide with the water *to form a mixture*” is followed by step “d. adding an aqueous source of an alkali metal or earth alkali metal hydroxide *to the mixture*,” indicating that step “c” must be performed before step “d.” The antecedent basis for each claimed step is annotated below:

1. A method of generating non-equilibrium solution of peracetic acid, comprising:
 - a. providing water;
 - b. introducing triacetin and aqueous hydrogen peroxide to the water;
 - c. mixing the triacetin and the aqueous hydrogen peroxide with the water to form a mixture;
 - d. adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture;
and
 - e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.

58. Additionally, a POSA would have understood that step “e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid” could not be performed out of order. Specifically, he or she would have understood that “a reaction medium” could only occur *after* all the required components have been added and mixed and hence could not logically be formed out of order. Put another way, “a reaction medium” would only be formed after steps (a) through (d) have provided all of the required components to create a reacting, “non-equilibrium solution of peracetic acid.”

59. Accordingly, in my opinion, a POSA would have understood that the claimed steps of the method of claim 1 of the '997 patent must be performed in the

recited order. Specifically, it requires (underlining and emphasis added) at least the order of steps of (a) first, “providing water;” (b) second, introducing triacetin and aqueous hydrogen peroxide to the water”; (c) third, “mixing the triacetin and the aqueous hydrogen peroxide with the water to form a mixture;” (d) fourth, “adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture;” and (e) fifth, “forming a reaction medium comprising a non-equilibrium solution of peracetic acid.”

60. Claim 8 of the '997 patent recites “[t]he method of claim 1, wherein step (d) is performed simultaneously with step (b).” In my opinion, this language of claim 8 fails to comply with the expressly recited language of claim 1 and hence improperly renders recited limitations in claim 1 superfluous and/or meaningless. Step (d) requires (underlining and emphasis added) that the “aqueous source of an alkali metal or earth alkali metal hydroxide” be added “to the mixture.” “The mixture” to which the “aqueous source of an alkali metal or earth alkali metal hydroxide” is added does not even exist in the claim until after step (c) of “mixing the triacetin and the aqueous hydrogen peroxide with the water *to form a mixture.*” Step (c) of claim 1 hence cannot logically be performed prior to step (b) because it is impossible to perform “mixing” of “the triacetin and the aqueous hydrogen peroxide with the water” (step c.) before the triacetin and the aqueous hydrogen peroxide has already been introduced to “the water” (step b.). Thus, claim 8 renders

the plainly step-ordered method in claim 1 ambiguous, superfluous, and indefinite. I understand from counsel that indefiniteness of a patent claim cannot be raised in an IPR proceeding. Nevertheless, for the foregoing reasons, it is my opinion that claim 8 of the '997 patent would not have caused a POSA to interpret the expressly recited language of claim 1 to ***not*** require the listed steps to be performed in the recited order.

61. For the purposes of my opinions expressed herein, therefore, I interpret claim 1 of the '997 patent as requiring that the listed steps be performed in the order expressly provided in the claim, except and unless expressly identified otherwise. I understand that in the district court proceedings, Patent Owner contends that the method recited in claim 1 does not require the steps to be performed in the recited order. However, in my opinion, Patent Owner's interpretation of the method of claim 1 as not requiring any order for the recited steps is directly contrary to the plain meaning of the claim language.

IX. OVERVIEW OF THE PRIOR ART RELIED UPON BY PETITIONER

A. JP 2006-045147 A ("Okano") (EX1005)

62. JP 2006-045147 A ("Okano") was filed as application JP2004-230323 on August 6, 2004, and published on February 16, 2006, thus making this Japanese patent application a prior art with respect to the '997 patent. (EX1005 (Okano), Page 1.)

63. According to Okano's Abstract, its disclosure is directed to "a sterilizing cleaner composition for hard surfaces." The Abstract further states that the composition contains:

water and an organic peracid obtained by reacting (A) an ester of a polyhydric alcohol and an organic acid with (B1) hydrogen peroxide in a specific molar ratio in water at a pH of 8 to 12, and having a pH of 1 or more and less than 7 at 25°C.

(EX1005 (Okano), Page 1.)

64. Okano explains that component (A) is "an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group[,]" and that "hydrogen peroxide" is "referred to as component (B1)." (EX1005 (Okano), [0008].) Okano further states that "triacetin is preferable" as "component (A)." (EX1005 (Okano), [0014].)

65. Thus, as part of the creation of the "sterilizing cleaner composition," Okano teaches the generation of PAA by creating a reaction mixture containing an acetyl precursor (A) (*i.e.*, an ester of a polyhydric alcohol and an organic acid, such as the preferred ester triacetin) and hydrogen peroxide (B1) under alkaline conditions (*i.e.*, a pH in the range of 8 to 12).

66. Okano further discloses using a relatively concentrated hydrogen peroxide-acetyl precursor solution to generate the PAA contained in the disclosed sterilizing cleaner composition. In this regard, Okano generally states that "[t]he

sterilizing cleaner composition for hard surfaces of the present invention can be prepared from a composition for producing sterilizing cleaner as described below.” (EX1005 (Okano), [0027].) Okano discloses that one such “first composition for producing sterilizing cleaner” contains a relatively concentrated mixture of component (A) and (B1) hydrogen peroxide and “ha[s] a water content of 1 to 25% by weight[.]” (EX1005 (Okano), [0028] (“hereinafter referred to as the first composition for producing sterilizing cleaner”).) Okano further discloses that this “first composition for producing sterilizing cleaner” containing component (A) and component (B1) has a relatively low water content of “1 to 25 wt%, preferably 5 to 20 wt%, and particularly preferably 5 to 15 wt%” in order to “suppress reaction between component (A) and component (B1) during storage and maintain the stability of the [first] composition[.]” (EX1005 (Okano), [0034].)

67. Okano describes the “first composition” of a relatively concentrated mixture of component (A) and hydrogen peroxide (B1) as “a single-liquid liquid composition containing components for obtaining an organic peracid[.]” and that such “first composition” is in the form of a “solution.” (EX1005 (Okano), [0035], [0036] (“The pH ([at] 20°C) of *the original solution of the first composition* for producing sterilizing cleaner ...” (emphasis added).) Furthermore, Okano discloses that the “first composition” solution may also include a “solvent” and notes that “a polyhydric alcohol solvent is preferable, and a glycol solvent such as propylene

glycol is even more preferable.” (EX1005 (Okano), [0036].)

68. Okano discloses that within the “first composition,” component (A) “is preferably 20 to 90 wt%, further [preferably] 30 to 90 wt%, and even more preferably 40 to 80 wt%,” and that “the amount of component (B1) is preferably 1 to 30 wt%, more so 5 to 25 wt%, and even more preferably 10 to 25 wt%.” (EX1005 (Okano), [0035].) Okano also teaches that the peracid included within the sterilizing cleaner composition is “obtained by reacting component (A) and component (B1) in water in a molar ratio of (A)/(B1) = 1/10 to 20/1 and at a pH of 8 to 12[.]” (EX1005 (Okano), [0015].)

69. Example 1 of Okano discloses a method for the “Preparation of Sterilizing Cleaner Composition (I)” that results in a peracetic acid (*i.e.*, “the organic peroxy acid”) solution as follows:

<Preparation of Sterilizing Cleaner Composition (I)>

(A) 50 g of triacetin (made by Cognis Japan, active ingredient 100%) and (B) 25 g of hydrogen peroxide (made by Ube Chemira, active ingredient 60%) were mixed with 850 g of ion exchanged water, 75 g of an alkaline aqueous solution containing 27% sodium hydroxide and 1.3% of organic phosphonic acid (product name: Dequest 2010, made by Solucia) was poured in, and this was then mixed and stirred for 5

minutes. Afterward, 75 g of a mixed acid solution containing 30% sulfuric acid and 6% phosphoric acid was immediately added to prepare the sterilizing cleaner composition (I) containing the organic peroxy acid. The pH ([at] 25°C) of the composition (I) was about 2, and the hydrogen peroxide content was about 1500 ppm.

(EX1005 (Okano), [0057].)

B. WO 2001/046519 (“Withenshaw”) (EX1006)

70. WO 2001/046519 (“Withenshaw”) is an International PCT publication titled “Peroxyacid Delivery Process.” (EX1006 (Withenshaw), Cover Page.) Withenshaw was published on June 28, 2001, and is therefore prior art to the ’997 patent.

71. Withenshaw discloses a “Peroxyacid Delivery Process” for the continuous generation of peroxyacid from hydrogen peroxide solution and a “bleach activator” (*i.e.*, an acetyl precursor), which may be used for pulp bleaching in papermaking. (*E.g.*, EX1006 (Withenshaw), Abstract.) The process disclosed in Withenshaw includes the hydrogen peroxide and acetyl precursor being added into water and mixed together in a mixing tank; thereafter, the water-hydrogen peroxide-acetyl precursor solution is combined and mixed with an alkaline material (such as sodium hydroxide) to initiate the alkali-catalyzed generation of peracetic acid within

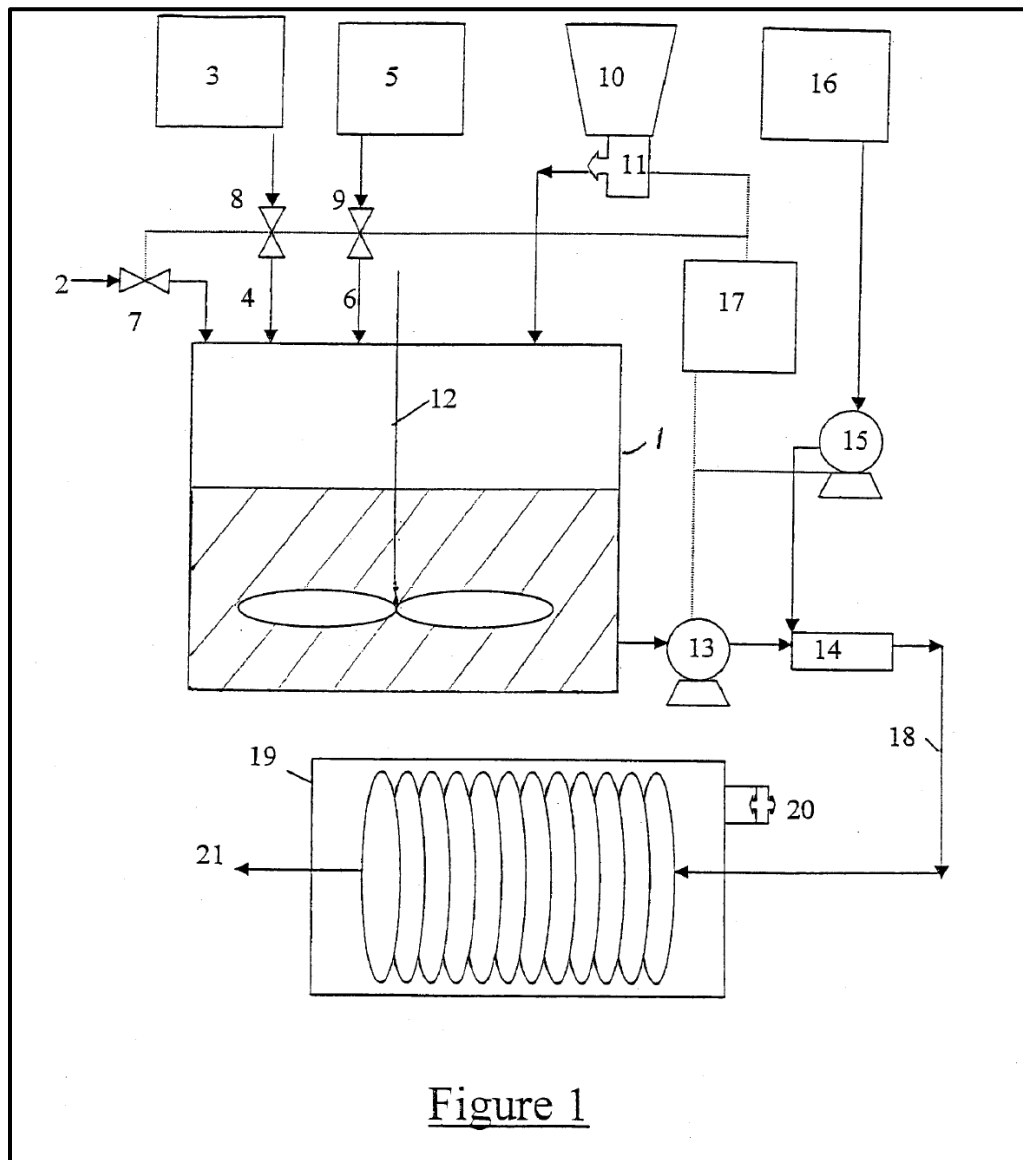
a tubular reactor. (EX1006 (Withenshaw), Abstract, 3:6-13 (“The present invention provides a peroxyacid delivery process for the continuous generation of peroxyacid from hydrogen peroxide solution and bleach activator characterised in that the pH of a mixture of hydrogen peroxide solution and bleach activator is adjusted by the addition or injection of an alkaline material selected from the group consisting of sodium hydroxide ... under vigorous mixing conditions provided by an in-line mixer within which the Froude number is at least 1, or by another mixer or combination of mixers providing an equivalent speed and intimacy of mixing”).)

72. Withenshaw’s process design discloses “the injection of the alkaline material in an essentially enclosed part of the system under continuous flow conditions between the supply of mixed hydrogen peroxide and activator” and provides “a continuous supply outlet for the peroxyacid containing product.” (EX1006 (Withenshaw), 3:29-4:2.) Withenshaw also teaches the preferred use of the acetyl precursor tetraacetylenediamine (TAED) as the “activator” and sodium hydroxide to provide an alkaline pH to increase PAA’s yield. (EX1006 (Withenshaw), 4:14-26, 5:6-11.)

73. Withenshaw further discloses a system for the continuous generation of PAA using a water-fed, stirred tank containing a mixture of water, hydrogen peroxide, and an acetyl precursor (TAED) that outputs an aqueous feed stream

containing the hydrogen peroxide and acetyl precursor that is co-fed into a mixer with the alkaline material to adjust the pH and to form the PAA reaction product in

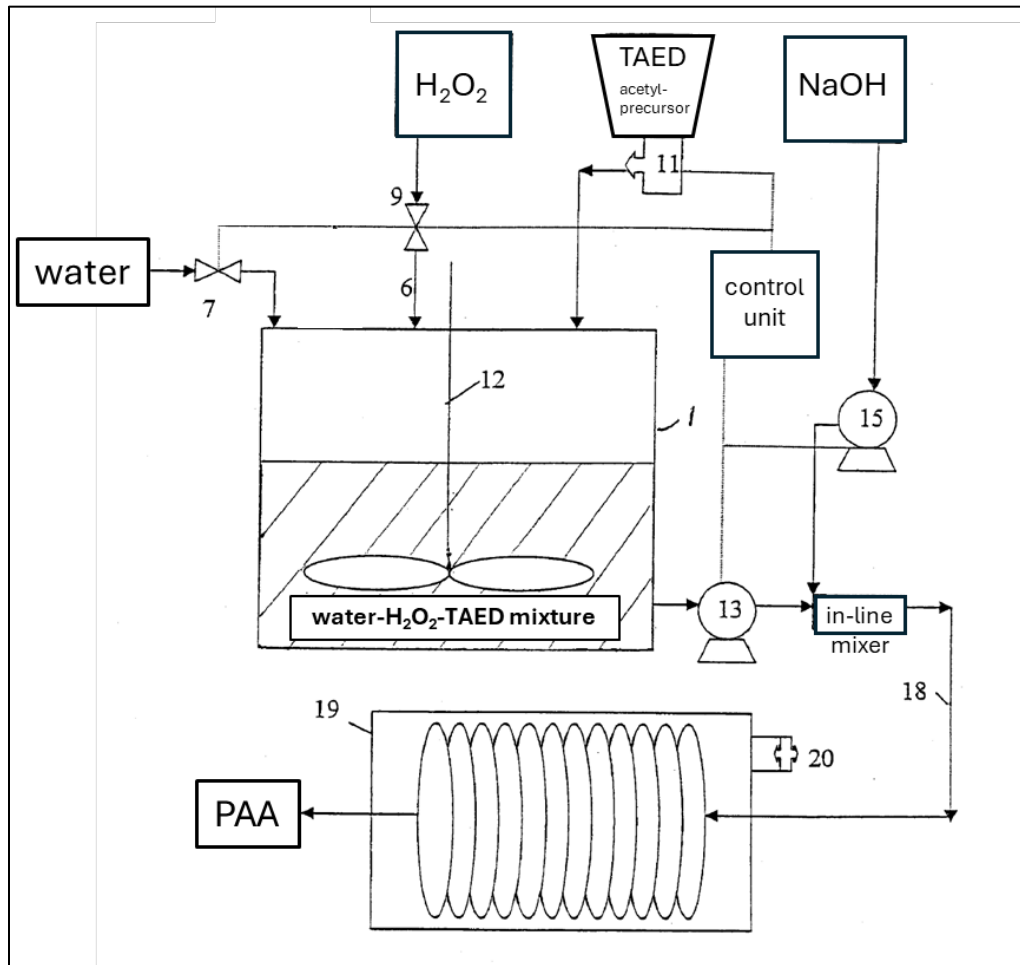
Figure 1:



(EX1006 (Withenshaw), Figure 1, 3:6-15, 4:27-28, 5:1-2, 8:27-29.)

74. In Withenshaw, water is fed through pipe 2, hydrogen peroxide is fed

from tank 5, and the acetyl precursor (here, an agglomerated TAED solid) from hopper 10 is fed into batch make-up tank 1 and mixed using agitator 12. (EX1006 (Withenshaw), 8:14-19; *see also id.* 8:27-9:10.) The mixture containing TAED, hydrogen peroxide, and water of batch make-up tank 1 is fed by pump 13 to in-line mixer 14 where sodium hydroxide is introduced via pump 15 in sufficient quantity to give the required alkaline pH at the end of the reaction, *e.g.*, at or near the end 21 of pipe 18. (EX1006 (Withenshaw), 9:11-14, 8:19-20.) The in-line mixer 14 creates turbulent flow, causing mixing of the sodium hydroxide and the aqueous TAED/hydrogen peroxide mixture, and thus leading to the reaction progressing rapidly and as a homogeneous solution. (EX1006 (Withenshaw), 9:24-26.) An annotated version of the schematic of Withenshaw's Figure 1 according to the foregoing descriptions with respect to the water, H₂O₂, TAED, and NaOH, as well as PAA generation, is provided below:



75. Withenshaw discloses that the reaction to form PAA within the in-line mixer can achieve greater than 85% conversion of TAED to PAA by controlling the reaction time through the flow rate and volume of pipe 18. (EX1006 (Withenshaw), 9:20-22.) To do so, Withenshaw teaches that the reaction “residence time is conveniently adjusted to suit the flow rate by adding or subtracting lengths of pipe.” (EX1006 (Withenshaw), 6:29-7:1.) Withenshaw further discloses that the reaction pipe can have “a residence time of between 4 and 25 min.” (EX1006 (Withenshaw), 4:27-28, 6:29-7:1.)

76. Withenshaw further explains that the disclosed system for the continuous production of PAA can be used in a batch-fed method wherein the batch make-up tank 1 is filled to its maximum capacity with a water-H₂O₂-TAED mixture and then emptied continuously until reaching a desired lower level, or after a defined period of time before the fill cycle starts again, or in an ongoing process wherein continuous metering pumps deliver all of the components on a continuous basis. (EX1006 (Withenshaw), 8:27-9:10.)

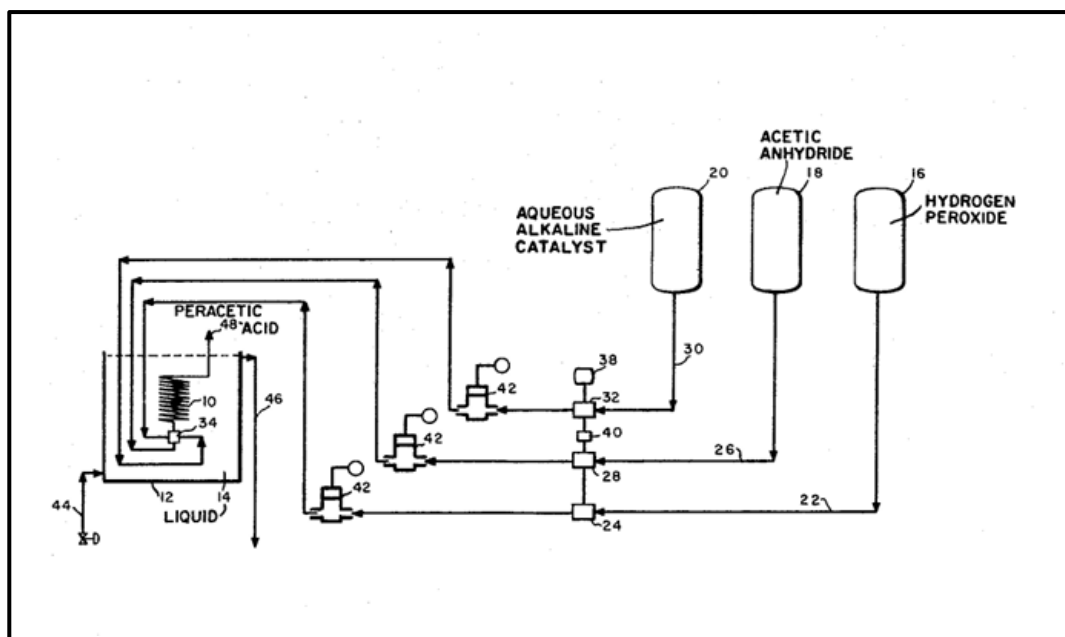
C. U.S. Patent No. 3,432,546 (“Oringer”) (EX1007)

77. U.S. Patent No. 3,432,546 (“Oringer”), titled “Manufacture of Peracetic Acid,” issued on March 11, 1969, and is therefore prior art to the ’997 patent. Oringer discloses a method using a tubular reactor for continuously generating PAA by reacting an acetyl precursor and hydrogen peroxide under alkaline conditions. (See EX1007 (Oringer), Abstract (1:11-21), 2:35-56.) Specifically, Oringer teaches:

A method for the production of an aqueous peracetic acid solution by the reaction of hydrogen peroxide with acetic anhydride in the presence of an alkaline catalyst comprising continuously introducing the reactants into a tubular reaction zone at a rate to produce a turbulent flow designated by a Reynolds number of 5,000 to 30,000 and a residence time in the reaction zone of 30 seconds to 5 minutes at a temperature of 80° to 140° F.

(EX1007 (Oringer), Abstract (1:11-21).)

78. Oringer further discloses a system for implementing the continuous production of a PAA aqueous solution according to the disclosed method. (EX1007 (Oringer), 5:21-24, Figure, 2:49-54 (“continuously withdrawing an aqueous peracetic acid reaction product”).) The reactor system configuration involves feed tanks containing hydrogen peroxide (16), acetic anhydride (*i.e.*, an acetyl precursor) (18), and an aqueous alkaline catalyst (20) that are fed into a mixer (34) tubular reactor (10) to continuously generate an aqueous peracetic acid reaction product (48), as follows:



(EX1007 (Oringer), 5:21-67, Figure.)

79. Oringer teaches that “[t]he combination of use of a tubular reaction

zone and a turbulent flow of reactants therethrough results in quite rapid and efficient production of a peracetic acid solution[,]” thereby achieving “very satisfactory yields in as little as about 30 seconds to one minute, although residence times of as much as 5 minutes can be tolerated safely due to the advantages of this method.” (EX1007 (Oringer), 4:16-24.)

X. SPECIFIC GROUNDS FOR INVALIDITY OF THE '997 PATENT

80. In my opinion, claims 1-14 of the '997 patent are invalid because they would have been obvious to a POSA based on the prior art. In this Declaration, I provide my opinions of obviousness based on the following three Grounds:

Ground	Claims	Opinions of Obviousness under 35 U.S.C. §103
1	1-7, 9-14	Obvious in view of Okano
2	1, 4, 5, 13-14	Obvious in view of the combination of Okano and Withenshaw
3	8	Obvious in view of the combination of Okano and Oringer

A. Ground 1: Claims 1-7 and 9-14 of the '997 Patent are Obvious Based on Okano

1. Claim 1 is obvious in view of Okano

a) 1[pre] “A method of generating a non-equilibrium solution of peracetic acid, comprising:”

81. I have been informed by counsel that in the Texas District Court litigation involving the '997 patent, the parties (*i.e.*, Clean Chemistry and Enviro

Tech Chemical Services, Inc.; in this proceeding, Petitioner and Patent Owner, respectively) have agreed that the preamble of this claim (“1[pre]”) is not limiting. Nevertheless, in my opinion, even if the preamble were limiting, it is disclosed by Okano.

82. Okano discloses that its “present invention” relates to a sterilizing composition “containing water and an organic peracid obtained by reacting (A) an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group that may have a hydroxyl group (herein referred to as component (A)) and (B1) hydrogen peroxide (herein referred to as component (B1)) in water at a molar ratio of (A)/(B1) = 1/10 to 20/1 and at a pH of 8 to 12, and which has a pH of 1 or more to 7 or less[.]” (EX1005 (Okano), [0008].) Okano discloses that “Component (A)” is “preferably an ester of glycerin and an aliphatic monocarboxylic acid having 1 to 8 carbon atoms, and among these, triacetin is preferable.” (EX1005 (Okano), [0011]-[0014].) Okano also discloses that “Component (B1)” is hydrogen peroxide and that “Component (B),” is “preferably hydrogen peroxide when the composition for producing sterilizing cleaner is liquid[.]” (EX1005 (Okano), [0030]-[0033].)

83. Okano further discloses that “[t]he component (A) and the component (B1) react under alkaline conditions ... in water to generate an organic peroxy acid, and therefore, a component that gives such a pH may be used as the component (C). Specifically, examples include alkali metal hydroxides such as sodium

hydroxide....” (EX1005 (Okano), [0048].) Okano therefore discloses a method for generating a non-equilibrium solution of peracetic acid when Okano’s preferred triacetin was used as component (A) and reacted with hydrogen peroxide (B1) under alkaline conditions (*e.g.*, a pH of 8 to 12). Thus, Okano discloses and hence renders obvious “[a] method of generating a non-equilibrium solution of peracetic acid,” which is claimed in 1[pre] of the ’997 patent.

84. Additionally, Okano’s Example 1 discloses a specific “method of generating a non-equilibrium solution of peracetic acid” by forming a solution containing 50 g of triacetin (pure), 25 g of hydrogen peroxide (60% aqueous solution), and 850 g of water to which “75 g of an alkaline aqueous solution containing 27% sodium hydroxide and 1.3% of organic phosphonic acid (product name: Dequest 2010, made by Solucia) was poured in, and this was then mixed and stirred for 5 minutes.” (EX1005 (Okano), [0057].) A POSA would have understood that the addition of “75 g of an alkaline aqueous solution containing 27% sodium hydroxide” would markedly raise the pH of the solution such that the triacetin and the hydrogen peroxide would begin reacting with each other to form peracetic acid—*i.e.*, begin “generating [a] non-equilibrium solution of peracetic acid. Thus, Okano also discloses the preamble of claim 1 of the ’997 patent as part of the method disclosed in Example 1.

85. Therefore, in my opinion, Okano discloses and hence renders obvious

the “[a] method of generating a non-equilibrium solution of peracetic acid” claim limitation of 1[pre].

b) 1[a] “a. providing water;”

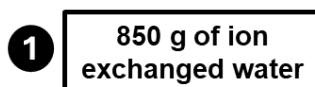
86. In my opinion, Okano discloses this claim limitation of the ’997 patent for the following reasons.

87. The method in Okano provides water to the sterilizing composition. Okano teaches that the “sterilizing cleaner composition for hard surfaces of the present invention contains *water* and an organic peracid obtained by reacting component (A) and component (B1) *in water* in a molar ratio of (A)/(B1) = 1/10 to 20/1 and at a pH of 8 to 12 ... That is, as described above, the sterilizing cleaner composition for hard surfaces of the present invention is prepared by reacting component (A) and component (B1) in *water*[.]” (EX1005 (Okano), [0015] (emphasis added); *see also id.*, [0029]-[0030].) A POSA would have understood that it would be typical and common to react the components in water by adding component (A) and component (B1) to water to form an aqueous reaction medium. Because the organic peracid is obtained by reacting the components in water, a POSA would have found it obvious that water would be provided prior to adding the component (A) and component (B1). Thus, Okano discloses the step of “providing water” of claim 1[a] of the ’997 patent.

88. The method step of “providing water” is also disclosed in Okano’s

Example 1 which describes a method for the “Preparation of Sterilizing Cleaner Composition” wherein “(A) 50 g of triacetin (made by Cognis Japan, active ingredient [content] 100%) and (B) 25 g of hydrogen peroxide (made by Ube Chemira, active ingredient [content] 60%) were mixed with 850 g of ion exchanged water[.]” (EX1005 (Okano), [0057].) A POSA would have recognized that, in order for the triacetin and hydrogen peroxide to be “mixed with 850 g of ion exchanged water” the 850 g of water must necessarily have been provided. A POSA would have understood that it is typical and common for the reactants, such as hydrogen peroxide and triacetin, to be added to water and that the 850 g of water in Example 1 would, therefore, have been provided before the two reactants can be added to it. This is generically depicted as an initial step (1) in Okano’s Example 1 below:

Okano – Example 1 ([0057])



89. Thus, Okano discloses and hence renders obvious a method that includes the initial step of “providing water” in claim1[a] of the ’997 patent.

c) 1[b] “b. introducing triacetin and aqueous hydrogen peroxide to the water;”

90. In my opinion, Okano discloses the step of “introducing triacetin and aqueous hydrogen peroxide to the water.” Specifically, Okano discloses that its

“present invention is prepared by reacting component (A) and component (B1) *in water* in a specific molar ratio at a pH of 8 to 12, and then adjusting the pH to 1 or more and less than 7, preferably 1 to 6 and more preferably 1 to 5.” (EX1005 (Okano), [0009], [0015].)

91. Regarding component (A), Okano expressly teaches that triacetin is the preferred acetyl precursor for a reaction with hydrogen peroxide. In particular, Okano discloses that “<Component (A)> [is] [a]n ester between a polyhydric alcohol and an organic acid having a hydrocarbon group, which ... component (A) *reacts with hydrogen peroxide* to produce an organic peracid ... Specifically, the component (A) is preferably an ester of glycerin and an aliphatic monocarboxylic acid having 1 to 8 carbon atoms, and *among these, triacetin is preferable.*” (EX1005 (Okano), [0011]-[0014] (emphasis added); *see also* Okano, [0057] (exemplary method using triacetin as component (A)).)

92. In addition to the foregoing explicit disclosure of the use of hydrogen peroxide as the oxidizing agent, Okano repeatedly discloses that “Component B” in the solution can be (and preferably is) hydrogen peroxide, identified either as component “(B1) hydrogen peroxide” or that it can be introduced through component (B2), which is “an inorganic peroxide which releases hydrogen peroxide into water.” (*See* EX1005 (Okano), [0008] (“hydrogen peroxide (herein referred to as component (B1))”), [0028]-[0030] (“A composition for producing sterilizing

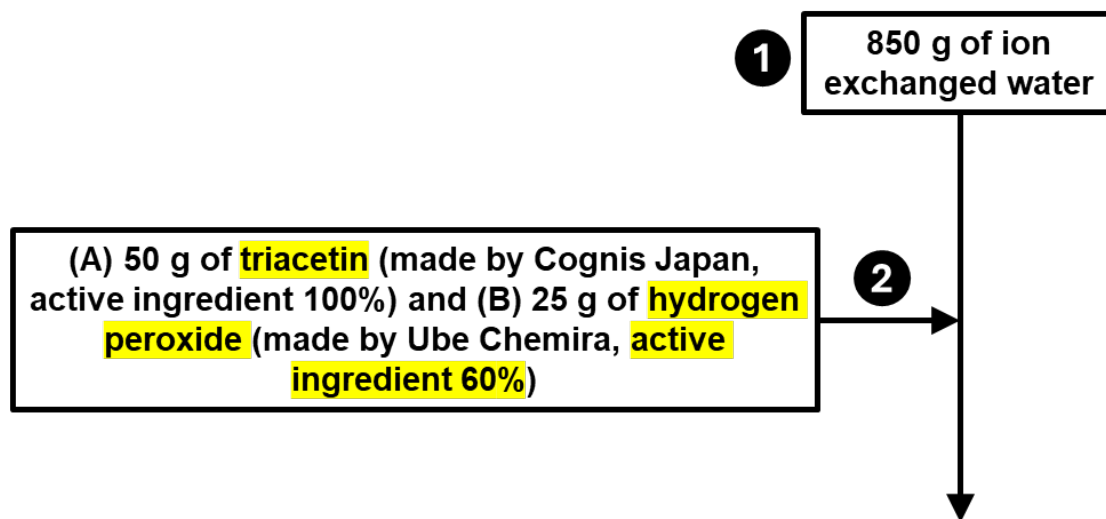
cleaner, containing (A) ... and (B1) hydrogen peroxide, and having a water content of 1 to 25% by weight (hereinafter referred to as the first composition for producing sterilizing cleaner), [0031] (“the inorganic peroxide that releases hydrogen peroxide in water (B2) ... the components (B1) and (B2) will be collectively described as component (B)”), [0057] (exemplary method using hydrogen peroxide as component (B)/(B1)).)

93. Accordingly, Okano discloses using triacetin as component (A) to generate peracetic acid by the reaction with hydrogen peroxide (B1) in water under alkaline conditions. (See EX1005 (Okano), [0015] (“The sterilizing cleaner composition for hard surfaces of the present invention contains water and an organic peracid obtained by reacting component (A) and component (B1) in water ...”), [0048] (“[t]he component (A) and the component (B1) react under alkaline conditions ... in water to generate an organic peroxy acid”), [0057] (exemplary generation of a PAA sterilizing solution using triacetin and hydrogen peroxide).)

94. Furthermore, Okano’s Example 1 discloses a method for introducing triacetin and aqueous hydrogen peroxide to the water. (EX1005 (Okano), [0057] (“Preparation of Sterilizing Cleaner Composition (I)”).) This example follows Okano’s general teachings of reacting (A) (*e.g.*, the preferred triacetin) and (B1) hydrogen peroxide “in a specific molar ratio *in water*.” (EX1005 (Okano), [Abstract] (emphasis added).)

95. Okano's Example 1 expressly discloses that “(A) 50 g of *triacetin* (made by Cognis Japan, active ingredient 100%) *and* (B) 25 g of *hydrogen peroxide* (made by Ube Chemira, active ingredient 60%) *were mixed with 850 g of ion exchanged water...*” (EX1005 (Okano), [0057] (emphases added).) By identifying the hydrogen peroxide as having “active ingredient 60%” indicates to a POSA that the hydrogen peroxide is “aqueous hydrogen peroxide” comprising 60% hydrogen peroxide and the remaining 40% of the “25g of hydrogen peroxide” being water. In my opinion, it would have been clear to a POSA that Okano's specifically disclosed amounts of 50 g of 100% triacetin and 25g of 60% aqueous hydrogen peroxide in Example 1 would have been introduced to the 850 g of water as a step that would necessarily have to occur for the triacetin, aqueous hydrogen peroxide, and water to be “mixed,” as depicted below as step 2:

Okano – Example 1 ([0057])



96. Accordingly, in my opinion, Okano discloses and hence renders obvious to a POSA the “introducing triacetin and aqueous hydrogen peroxide to the water” limitation of claim 1[b] of the ’997 patent and, moreover, that this claimed step necessarily occurs *after* “providing [the] water.”

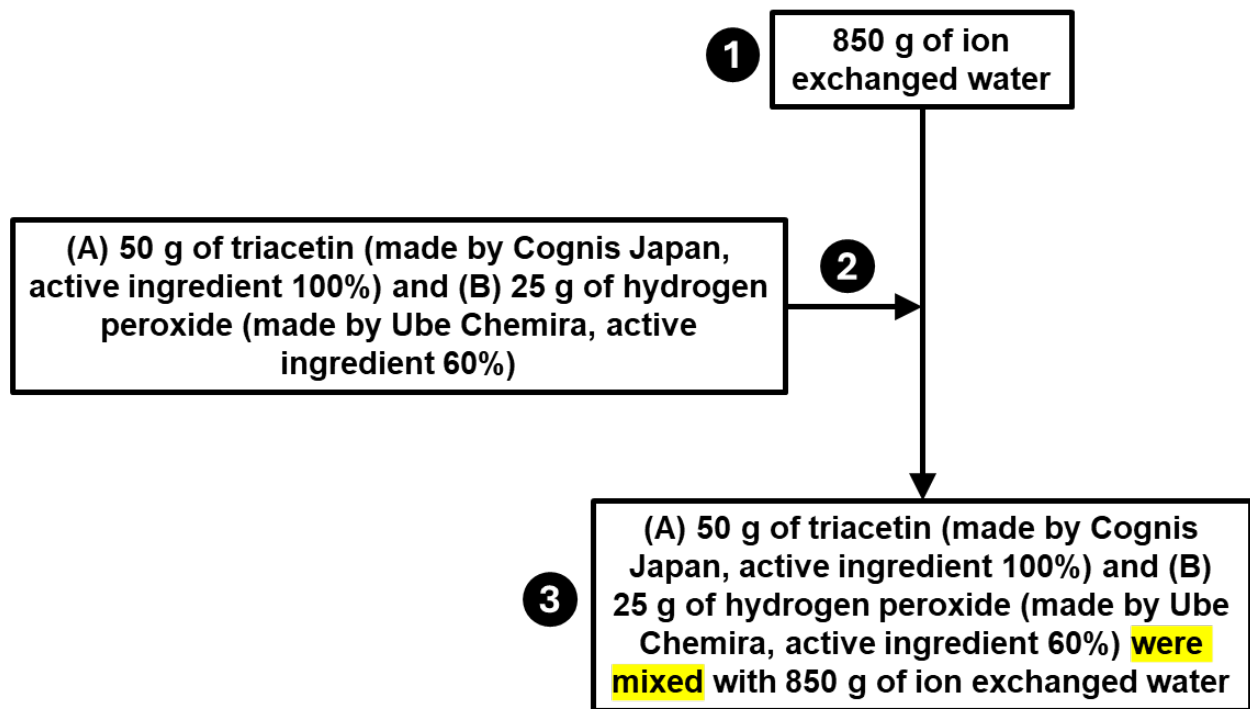
d) 1[c] “c. mixing the triacetin and the aqueous hydrogen peroxide with the water to form a mixture;”

97. In my opinion, Okano discloses and hence renders obvious the “mixing the hydrogen peroxide-triacetin solution and the water to form a mixture” claim limitation of the ’997 patent.

98. Okano discloses introducing triacetin and aqueous hydrogen peroxide to the water of the sterilizing composition, as discussed in the previous section.

Okano also expressly teaches a method of preparing a peracetic acid sterilizing cleaner solution wherein the triacetin and aqueous hydrogen peroxide is mixed with water. (EX1005 (Okano), [0057].) In particular, Okano's Example 1 expressly discloses that "(A) 50 g of triacetin (made by Cognis Japan, active ingredient 100%) and (B) 25 g of hydrogen peroxide (made by Ube Chemira, active ingredient 60%) *were mixed with 850 g of ion exchanged water...*" (EX1005 (Okano), [0057] (emphasis added).) This "mixing" step in Okano's Example 1 is depicted below as step 3:

Okano – Example 1 ([0057])



99. Thus, in my opinion, Okano discloses to a POSA the step of "mixing

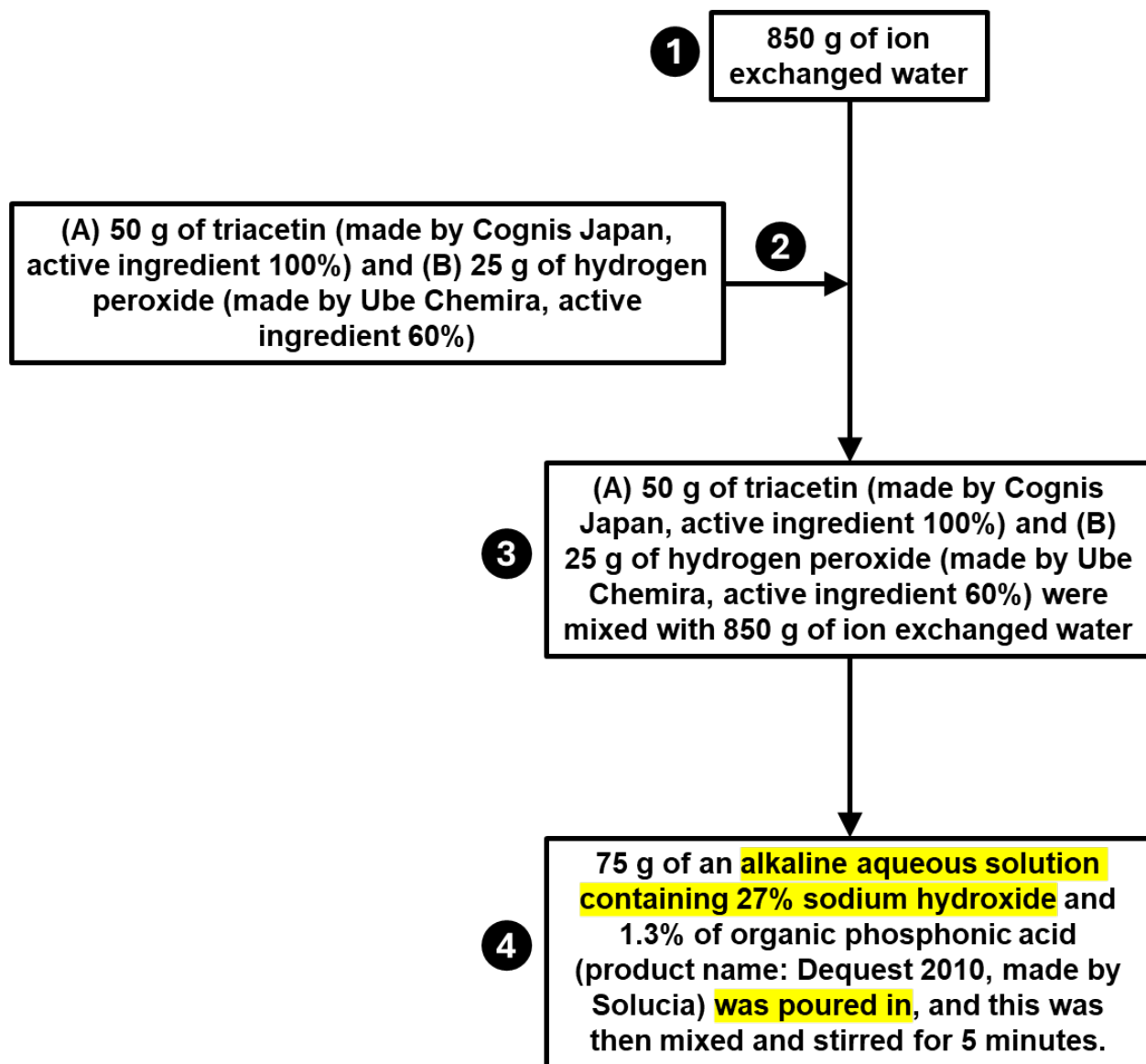
the triacetin and the aqueous hydrogen peroxide with the water to form a mixture” and that this step occurs *after* the claimed step of “introducing a hydrogen peroxide-triacetin solution to the water.”

e) 1[d] “d. adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture; and”

100. In my opinion, Okano discloses and hence renders obvious this claim limitation of the '997 patent. Okano states that the sterilizing non-equilibrium solution of peracetic acid is prepared “by setting the pH to 8 to 12, preferably to 9 to 11” where “an alkaline pH adjusting agent is preferably used[.]” (EX1005 (Okano), [0039]; *see also* [0046] (“a reaction initiator (hereinafter referred to as component (C)) that initiates the reaction of component (A) and component (B1) brought about by the composition”).) Okano also discloses examples of such “alkaline pH adjusting agent[s],” which expressly includes sodium hydroxide. (EX1005 (Okano), [0040], [0048] (“component (A) and the component (B1) react under alkaline conditions (water temperature 5 to 50 is suitable) in water to generate an organic peroxy acid, and therefore, a component that gives such a pH may be used as the component (C). Specifically, examples include alkali metal hydroxides such as sodium hydroxide, potassium hydroxide, calcium hydroxide, and barium hydroxide, alkaline earth metal hydroxides”).) Thus, Okano discloses “adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture.”

101. Okano also teaches a preparation of the peracetic acid cleaning solution in Example 1 that includes adding an aqueous source of an alkali metal hydroxide to the mixture of triacetin, hydrogen peroxide, and water: “(A) 50 g of triacetin (made by Cognis Japan, active ingredient 100%) and (B) 25 g of hydrogen peroxide (made by Ube Chemira, active ingredient 60%) were mixed with 850 g of ion exchanged water, **75 g of an alkaline aqueous solution containing 27% sodium hydroxide** and 1.3% of organic phosphonic acid (product name: Dequest 2010, made by Solucia) **was poured in**, and this was then mixed and stirred for 5 minutes.” (EX1005 (Okano), [0057] (emphases added).) A POSA would have understood that first describing that triacetin, hydrogen peroxide, and 850 g of water “were mixed,” followed by the teaching that the “75 g of an alkaline aqueous solution containing 27% sodium hydroxide ... **was poured in**, and this was then mixed and stirred for 5 minutes” indicates that the alkaline aqueous solution containing the sodium hydroxide is added in a distinct step (*i.e.*, “poured in”) that occurs after the “mixture” containing the hydrogen peroxide (25 g, 60%)-triacetin (50 g, pure)-water (850 g) was already previously mixed. This step in Okano’s Example 1 is identified as step 4 in the figure below:

Okano – Example 1 ([0057])



102. Thus, in my opinion, a POSA would have understood that Okano discloses and hence renders obvious a method for creating a sterilizing cleaner solution with a step that includes the claim limitation “adding an aqueous source of

an alkali metal or earth alkali metal hydroxide to the mixture” of the ’997 patent and that this step occurs *after* the claimed step of mixing the triacetin and the aqueous hydrogen peroxide with the water to form a mixture.

f) 1[e] “e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.”

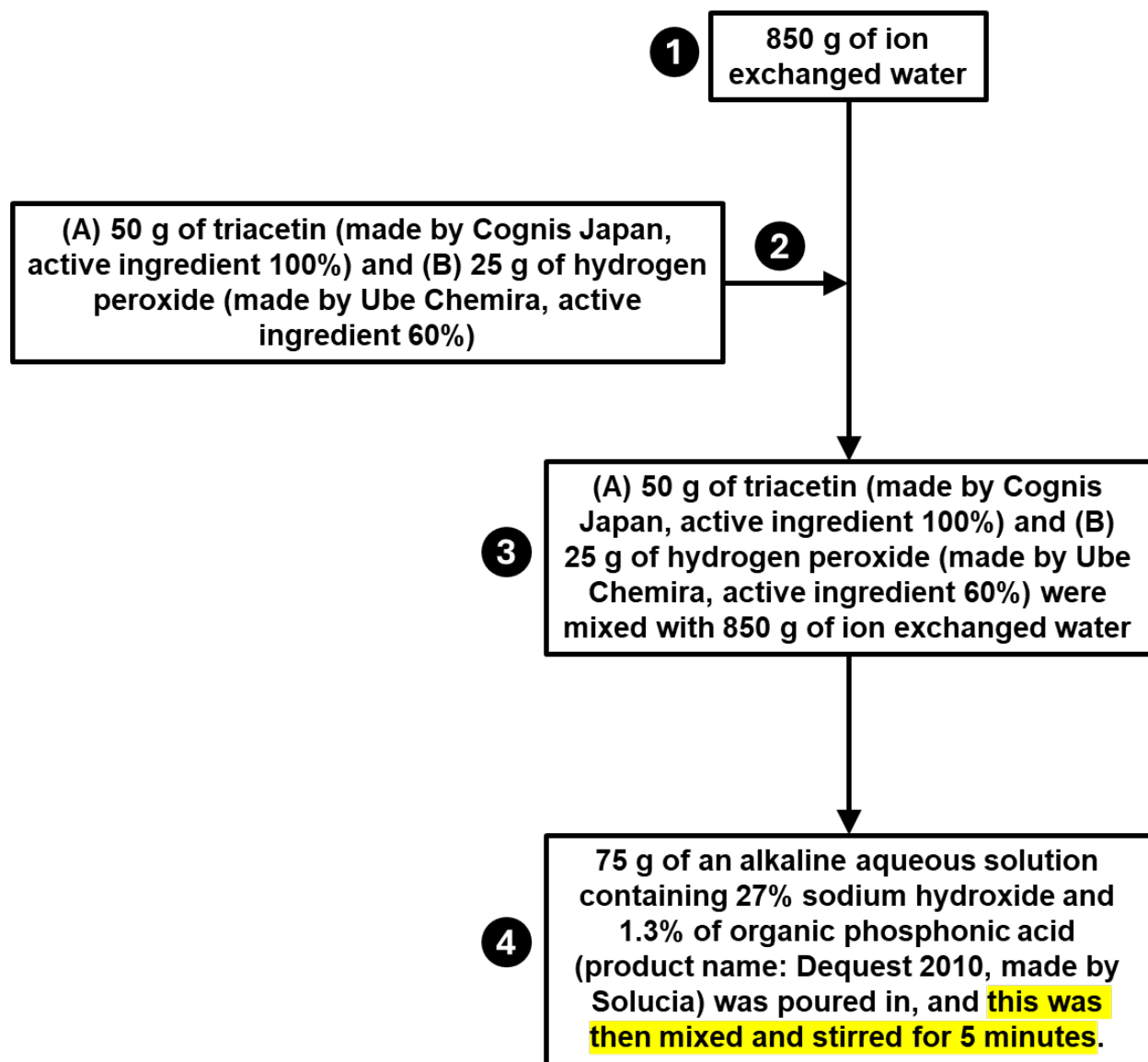
103. In my opinion, Okano discloses and hence renders obvious to a POSA this claim limitation of the ’997 patent. In particular, Okano discloses that “[t]he present invention relates to a sterilizing cleaner composition for hard surfaces, containing water and an organic peracid[.]” (EX1005 (Okano), [0008].)

104. As explained above, Okano teaches a method of preparing a non-equilibrium solution of peracetic acid by combining triacetin, hydrogen peroxide, and water with an alkaline source. (EX1005 (Okano), [0057].) Okano explains that “component (A) [preferably triacetin] and the component (B1) [hydrogen peroxide] react under alkaline conditions ... in water to generate an organic peroxy acid [PAA], and therefore, a component that gives such a pH may be used as the component (C).” (EX1005 (Okano), [0048].) Specifically, examples include alkali metal hydroxides such as sodium hydroxide....” (EX1005 (Okano), [0048].) Okano also discloses a “sterilizing cleaner kit” that contains “a reaction initiator (hereinafter referred to as component (C)) that initiates the reaction of component (A) and component (B1) brought about by the composition[.]” (EX1005 (Okano), [0046].) Thus, Okano

discloses the step of adding an alkali metal hydroxide such as sodium hydroxide (*i.e.*, reaction initiator component (C)) to the aqueous hydrogen peroxide-triacetin-water mixture to raise the pH to alkaline conditions in order to initiate the alkali-catalyzed generation of PAA, and thereby forming a reaction medium comprising a non-equilibrium solution of peracetic acid.

105. A POSA would have recognized that a reaction medium comprising a non-equilibrium solution of peracetic acid is also taught in Example 1 of Okano, which discloses that “75 g of an alkaline aqueous solution containing 27% sodium hydroxide ... was poured in, and ***this was then mixed and stirred for 5 minutes.***” (EX1005 (Okano), [0057] (emphasis added).) As noted above, Okano discloses that “component (A) [preferably triacetin] and the component (B1) [hydrogen peroxide] react under alkaline conditions ... in water to generate an organic peroxy acid [PAA]” (EX1005 (Okano), [0048]), which satisfies the claimed step of “forming a reaction medium comprising a non-equilibrium solution of peracetic acid” of the ’997 patent, as shown in the image depicted below as step 4 of Okano’s Example 1:

Okano – Example 1 ([0057])



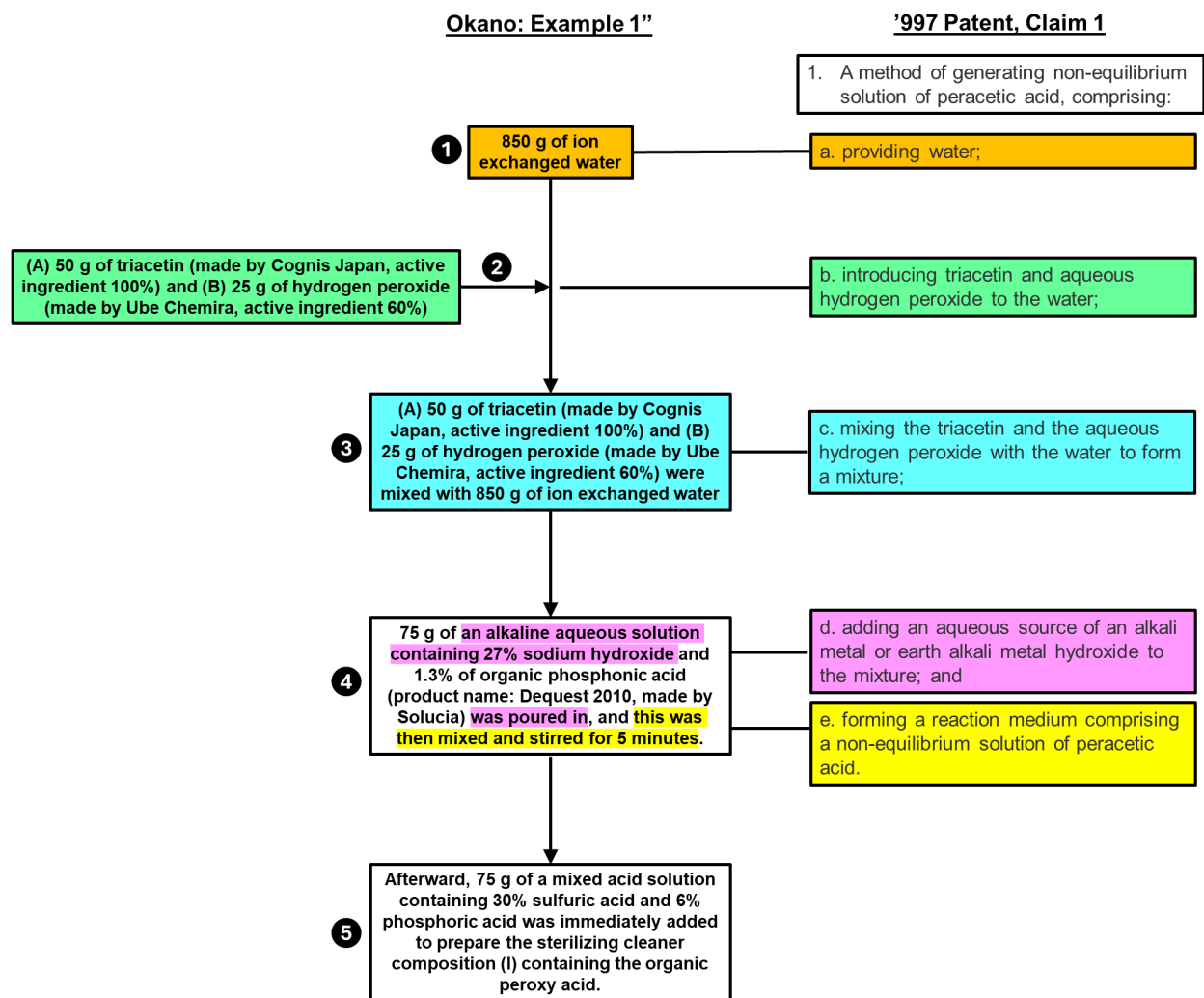
106. Okano's Example 1 further discloses that, after stirring the reaction mixture for 5 minutes, "75 g of a mixed acid solution containing 30% sulfuric acid and 6% phosphoric acid was immediately added to prepare the sterilizing cleaner composition (I) containing the organic peroxy acid" and that the resulting "hydrogen

peroxide content was 1500 ppm.” (EX1005 (Okano), [0057].) A POSA would have understood that 1500 ppm (*i.e.*, parts per million) of residual hydrogen peroxide is about 0.15 wt% (*i.e.*, $100\% \times 1500/1,000,000$) or a residual mass of hydrogen peroxide of about 1.5 g in the 1000-g mixture. Since the amount of input hydrogen peroxide in Okano’s Example 1 was 15 g (*i.e.*, 60% of the 25 g of aqueous hydrogen peroxide added), Okano discloses that roughly 90% ($100\% \times (15 \text{ g} - 1.5 \text{ g}) / 15 \text{ g}$) of the hydrogen peroxide was reacted to generate the non-equilibrium reaction solution of PAA.

107. In sum, Okano’s Example 1 satisfies all limitations of claim 1, as follows:

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108. Accordingly, because all elements of claim 1 are disclosed and hence rendered obvious by Okano, claim 1 of the '997 patent is invalid.

2. Claim 2: "The method of claim 1, wherein the triacetin and the aqueous hydrogen peroxide are introduced simultaneously."

109. In my opinion, Okano discloses and hence renders obvious this claim of the '997 patent.

110. Okano discloses a "first composition for producing sterilizing cleaner"

which contains component (A), component (B1), and “in order to suppress reaction between component (A) and component (B1) during storage and maintain the stability of the composition,” a restricted water content of between 1 to 25 wt%, preferably 5 to 15 wt%. (EX1005 (Okano), [0034].) A POSA would have understood this as disclosing a hydrogen peroxide-acetyl precursor composition containing component (A), such as the preferred triacetin, and component (B1) hydrogen peroxide. (See EX1005 (Okano), [0035] (“the original solution of the first composition for producing sterilizing cleaner”)) Okano further teaches that the concentration of component (A) in the first composition for producing sterilizing cleaner is “even more preferably between 40 and 80 wt%,” the concentration of component (B1) is “even more preferably between 10 and 25 wt%,” and that the water content is “particularly preferably 5 to 15 wt%.” (EX1005 (Okano), [0035], [0034].)

111. Thus, Okano discloses generating peroxy acid sterilizing solutions from a relatively concentrated and premixed “first composition” containing both component (A) [preferably triacetin], hydrogen peroxide (B1), and low water content. (See EX1005 (Okano), [0027] (“The sterilizing cleaner composition for hard surfaces of the present invention can be prepared from a composition for producing sterilizing cleaner as described below.”), [0028] (“the first composition for producing sterilizing cleaner”), [0034]-[0036] (“First Composition for Producing

Sterilizing Cleaner”).) Given that Okano preferred component (A) is preferably triacetin, a POSA reading Okano would have understood that the first composition for producing sterilizing cleanser is a hydrogen peroxide-triacetin composition with low water content where the triacetin and hydrogen peroxide are premixed together for use in generating the sterilizing composition.

112. A POSA would have recognized that the amounts of triacetin and hydrogen peroxide in Example 1 correlate to the most preferred values taught for Okano’s “first composition,” thereby showing that the example is ideally suited for use with Okano’s “first composition” disclosures. In this regard, 50 g of 100% triacetin and 25 g of 60% hydrogen peroxide as used in Example 1 equates to a “first composition” containing 67% of triacetin, 20% of hydrogen peroxide, and 13% of water. These values correspond to, and fall well within, the most preferred concentrations for these components in the “first composition” disclosed in Okano: component (A), in this case triacetin, of “even more preferably 40 to 80 wt%” ([0035]); a concentration of (B1), hydrogen peroxide, of “even more preferably 10 to 25 wt%” ([0035]); and a water content of “particularly preferably 5 to 15 wt%” ([0034]). (EX1005 (Okano), [0034-0035].) That is, as further shown in the table below, a POSA would have understood that Okano discloses and teaches that the triacetin and hydrogen peroxide of Example 1 be introduced as a single “first composition for producing a sterilizing cleaner” solution because the amounts of

triacetin, hydrogen-peroxide, and water in the components of Example 1 match and fall within the most preferred ranges of Okano's disclosed "first composition":

Okano's Disclosure	"The <i>first composition for producing a sterilizing cleaner</i> of the present invention contains component (A) and component (B1)" (EX1005 (Okano), [0034]-[0035] (emphasis added))	Example 1: "(A) 50 g of triacetin (made by Cognis Japan, active ingredient 100%) and (B) 25 g of hydrogen peroxide (made by Ube Chemira, active ingredient 60%)" (EX1005 (Okano), [0057])
triacetin	40-80 wt% ¹	67 wt%
hydrogen peroxide	10-25 wt% ²	20 wt%
water	5-15 wt% ³	13 wt%

113. A POSA would also have recognized that such a "first composition" according to Okano's Example 1 would have 0.23 moles (50 g) of triacetin and 0.44 moles (15 g) of hydrogen peroxide, which gives a mole ratio of triacetin (A)/hydrogen peroxide (B) of 0.52, and also falls within the "even more preferably 1/5 to 10/1" molar ratio disclosed and taught by Okano for the "first composition."

¹ See EX1005 (Okano), [0035] ("The amount of component (A)...even more preferably 40 to 80 wt%"); see also Okano, [0014] ("component (A)...triacetin is preferable").

² See EX1005 (Okano), [0035] ("the amount of component (B1)...even more preferably 10 to 25 wt%"); see also Okano, [0009] ("(B1) hydrogen peroxide"), [0029] ("(B1) hydrogen peroxide"), [0030] ("(B1) hydrogen peroxide").

³ See EX1005 (Okano), [0034] ("the moisture content of the composition is...particularly preferably 5 to 15 wt%").

(EX1005 (Okano), [0035].) Additionally, the molar ratio of hydrogen peroxide (component (B1)) per ester group of triacetin (component (A)) in Example 1 is 0.64 (based on the ratio of 0.44 moles of hydrogen peroxide / (3 x 0.23 moles triacetin)). This number also falls well within the “particularly preferable” ratio value of “0.3 to 2, from the viewpoints of efficiently generating an organic peracid and reducing unreacted hydrogen peroxide” taught by Okano. (EX1005 (Okano), [0035].)

114. In sum, Okano’s Example 1 discloses amounts of triacetin, aqueous hydrogen peroxide, and water consistent with all of the most preferred features of Okano’s “first composition for producing a sterilizing cleaner” in its paragraphs [0034]-[0035]. Accordingly, in my opinion, a POSA would have found the triacetin and hydrogen peroxide components of Okano’s Example 1 as ideally suited to be combined into a single “first composition” for producing the sterilizing cleaner of Okano’s “present invention.” (*See, e.g.*, EX1005 (Okano), [0034].) The use of this “first composition” within Example 1 in Okano would entail creating a “first composition” containing 50 g of triacetin and 25 g of 60% hydrogen peroxide and then introducing and mixing this triacetin-aqueous hydrogen peroxide composition with the water. Thus, Okano discloses the formation of a triacetin and aqueous hydrogen peroxide “first composition” that would be introduced simultaneously to the water, thereby satisfying the step of claim 2.

115. It is, therefore, my opinion that Okano renders claim 2 of the ’997

patent obvious.

3. Claim 3: “The method of claim 1, wherein the triacetin and the aqueous hydrogen peroxide are introduced sequentially with either one first.”

116. Okano discloses and hence renders obvious “wherein the triacetin and the aqueous hydrogen peroxide are introduced sequentially with either one first” as recited in claim 3 of the ’997 patent. As explained above, Okano’s component A is preferably triacetin and component (B1) is hydrogen peroxide, such as in Okano’s Example 1. (*E.g.*, EX1005 (Okano), [0057].)

117. Okano’s Example 1 expressly discloses that “(A) 50 g of *triacetin* (made by Cognis Japan, active ingredient 100%) *and* (B) 25 g of *hydrogen peroxide* (made by Ube Chemira, active ingredient 60%) *were mixed with 850 g of ion exchanged water...*” (*Id.*, (emphasis added).) Identifying the hydrogen peroxide as having “active ingredient 60%” indicates to a POSA that the hydrogen peroxide is “aqueous hydrogen peroxide” comprising 60% hydrogen peroxide and the remaining 40% of the “25g of hydrogen peroxide” being water. In my opinion, it would have been clear to a POSA that Okano’s specifically disclosed amounts of 50 g of 100% triacetin and 25g of 60% aqueous hydrogen peroxide in Example 1 could and would have been introduced to the 850 g of water, and that the triacetin and the hydrogen peroxide could be introduced into the water sequentially with either one first.

118. Accordingly, in my opinion, Okano discloses and hence renders obvious a method for generating a non-equilibrium solution of PAA according to claim 1 (as discussed above) “wherein the triacetin and the aqueous hydrogen peroxide are introduced sequentially with either one first,” as recited in claim 3.

4. Claim 4: “The method of claim 1, wherein the provided water is an aqueous stream.”

119. Okano discloses and hence renders obvious the claim limitation of the '997 patent that “the provided water is in an aqueous stream.” In other words, a POSA would have found it obvious that water in Okano’s method for forming PAA from an aqueous solution containing triacetin and hydrogen peroxide was provided in the form of an aqueous stream. As explained above regarding claim element 1[a], Okano teaches the method step of providing water to which a triacetin-hydrogen peroxide “first composition” is added. Water, as a liquid under ambient conditions, is essentially always delivered or provided in the form of a stream and a stream of water is inherently an *aqueous* stream. Additionally, a POSA would have found it obvious for 850 g of water used in Okano’s Example 1 to be provided directly from a tap as an aqueous stream or poured in as an aqueous stream from a beaker or another container. Accordingly, it is my opinion that claim 4 of the '997 patent is obvious in view of Okano.

5. Claim 5: “The method of claim 1, wherein the provided water is contained in a mixing tank or other vessel.”

120. In my opinion, Okano discloses and hence renders obvious the claim limitation of the '997 patent that “the provided water is contained in a mixing tank or other vessel.” Okano’s Example 1 discloses that triacetin and hydrogen peroxide were “mixed” with 850 g of water. (EX1005 (Okano), [0057].) A POSA would have known that the 850 g of “the provided water” to which the reagents for generating PAA solution are added and mixed would necessarily have to be held in some type of reaction vessel since water is a liquid under ambient conditions that, unlike a solid, is not free-standing. Okano teaches that triacetin and hydrogen peroxide were “mixed” with 850 g of water, thus indicating that the vessel served as a mixing tank. Likewise, a POSA would have found it obvious for 850 g of “the provided water” to be added to the reaction vessel from another vessel, such as a beaker, pipe, or other container. Thus, claim 5 of the '997 patent is obvious in view of Okano.

6. Claim 6: “The method of claim 1, wherein the aqueous source of the alkali metal or earth alkali metal hydroxide is sodium hydroxide.”

121. In my opinion, Okano discloses and hence renders obvious that the claim limitation of the '997 patent “the aqueous source of the alkali metal or earth alkali metal hydroxide is sodium hydroxide.” Okano states that the sterilizing non-

equilibrium solution of peracetic acid is “prepared by setting the pH to 8 to 12, preferably to 9 to 11” where “an alkaline pH adjusting agent is preferably used[.]” (EX1005 (Okano), [0039].) Okano also discloses examples of such “alkaline pH adjusting agent[s],” which expressly include sodium hydroxide. (EX1005 (Okano), [0040] (“alkaline pH adjusting agents include alkali metal hydroxides such as sodium hydroxide”).) A POSA would, therefore, have understood that Okano expressly discloses sodium hydroxide as a prominent example of the “alkaline pH adjusting agent.”

122. Okano also specifically exemplifies a preparation of a peracetic acid solution generated by the addition of an aqueous sodium hydroxide solution to the aqueous triacetin-hydrogen peroxide-water mixture. (EX1005 (Okano), [0057] (“(A) 50 g of triacetin (made by Cognis Japan, active ingredient 100%) and (B) 25 g of hydrogen peroxide (made by Ube Chemira, active ingredient 60%) were mixed with 850 g of ion exchanged water, **75 g of an alkaline aqueous solution containing 27% sodium hydroxide** and 1.3% of organic phosphonic acid (product name: Dequest 2010, made by Solucia) **was poured in**, and this was then mixed and stirred for 5 minutes.”) (emphases added).) A POSA would have known that the “75 g of an alkaline aqueous solution containing 27% sodium hydroxide” that “was is poured in” the mixture in Okano’s Example 1 is an “aqueous source of the alkali metal or earth alkali metal hydroxide [that] is sodium hydroxide.”

123. Thus, a POSA would have found claim 6 of the '997 patent to be obvious in view of Okano.

7. Claim 7: “The method of claim 6, wherein the sodium hydroxide is about 1.82% to about 7.28%.”

124. In my opinion, Okano discloses and hence renders obvious the “wherein the sodium hydroxide is about 1.82% to about 7.28%” claim limitation of the '997 patent. As explained above with respect to claim 6, Okano discloses the use of sodium hydroxide as a pH adjusting agent for the generation of PAA. (EX1005 (Okano), [0040], [0057].) Okano's Example 1 teaches a method of generating PAA where 75 g of an aqueous solution containing 27% sodium hydroxide is added to the mixture. (EX1005 (Okano), [0057].) A POSA would have understood that 75 g of 27% sodium hydroxide is equal to 20 g ($75 \text{ g} \times 0.27$) of sodium hydroxide that is added to the mixture. A POSA would also have understood that the total mixture at step 4 (after the addition of the sodium hydroxide solution) includes 50 g of triacetin, 25 g of hydrogen peroxide solution, 850 g of water and 75 g of the sodium hydroxide aqueous solution, thereby totaling 1000 g. The amount of 20 g of sodium hydroxide in a 1000-g mixture is a 2% sodium hydroxide concentration. A POSA would have understood this 2% concentration of sodium hydroxide to fall well within the claimed range of “about 1.82% to about 7.28%” of claim 7 of the '997 patent.

125. Thus, a POSA would have found this patent claim obvious in view of Okano.

8. Claim 9: “The method of claim 1, further comprising allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid.”

126. In my opinion, Okano discloses and hence renders obvious the “allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid” claim limitation of the ’997 patent. Okano discloses that the molar/mole ratio of hydrogen peroxide per ester group of triacetin is “preferably mole increased by a factor of 2 or less, and particularly preferably mole increased by a factor of 0.3 to 2, from the viewpoints of *efficiently generating an organic peracid and reducing unreacted hydrogen peroxide.*” (EX1005 (Okano), [0035] (emphasis added).) Consistent with minimizing the amount of unreacted hydrogen peroxide in the generated PAA aqueous solutions, Okano further discloses that “it is preferable that the hydrogen peroxide content of the sterilizing cleaner composition for hard surfaces of the present invention is 0.5 wt% or less, more preferably 0.3 wt% or less, and even more preferably 0.2 wt% or less.” (EX1005 (Okano), [0023].) Thus, a POSA would have understood that the methods and resulting PAA solutions disclosed in Okano suggest “maximiz[ing] the conversion of the hydrogen peroxide triacetin into peracetic acid”

at a given molar/mole ratio of hydrogen peroxide per ester group of triacetin by providing reaction conditions that minimize the amount of unreacted hydrogen peroxide (*i.e.*, attaining “even more preferably 0.2 wt% or less” residual unreacted hydrogen peroxide), thereby “maximiz[ing] the conversion of the hydrogen peroxide triacetin into peracetic acid.

127. A POSA would have been motivated to optimize the conversion of Okano’s input reactants hydrogen peroxide and triacetin to PAA based on commonly known chemical reaction design principles seeking to improve cost-efficiency by minimizing the amount of unreacted remaining reactants that generate the PAA reaction product since they would amount to wasteful excess and unused raw materials. (*See, e.g.*, EX1013 (Hill), 245 (“[t]he chemical engineer is required to choose the reactor configuration and mode of operation that yields the greatest profit consistent with market constraints for the raw material”).) A POSA would have understood that, for example, the concentration of input reactants, their relative molar/mole ratio, and the reaction rate and time are all outcome-determinative variables that could and should be readily controlled to optimize the generation of PAA based on a desired output for such production. (*Id.* (“Usually there are many combinations of operating conditions and reactor size and/or type that will meet the requirements imposed by nature in terms of the reaction rate expression involved and those imposed by management in terms of the required production capacity.”)),

id., 246 (“there is often considerable freedom of choice available in terms of the type of reactor and reaction conditions that will accomplish a given task”).)

128. Okano’s Example 1 teaches that the combination of triacetin, hydrogen peroxide, water, and sodium hydroxide (at step 4) is “mixed and stirred for 5 minutes.” (EX1005 (Okano), [0057].) Coupled with Okano’s stated desire to “efficiently generat[e] an organic peracid and reduc[e] unreacted hydrogen peroxide,” (EX1005 (Okano), [0035]), a POSA would have understood and found obvious that Okano’s identified time of reaction under the conditions of Example 1 was likely meant to be consistent with Okano’s desired teaching of a method that allows the reaction medium sufficient time to efficiently convert the hydrogen peroxide and the triacetin into peracetic acid by reducing the amount of unreacted hydrogen peroxide. After 5 minutes, Okano’s Example 1 discloses the addition of an acid solution that changes the pH of the mixture from alkaline to very acidic (*i.e.*, to a pH of 2), thereby effectively quenching the conversion of hydrogen peroxide and triacetin to PAA.

129. Okano discloses that the amount of unreacted hydrogen peroxide in its Example 1 after 5 minutes of reaction under the specific conditions in that example is 1500 ppm. (EX1005 (Okano), [0057].) This amount of residual hydrogen peroxide (*i.e.*, 1500 ppm or 0.15 wt%) is within the maximum desired conversion of hydrogen peroxide to PAA taught by Okano since it falls within the smallest

identified range for the most preferred amount of residual hydrogen peroxide there. (EX1005 (Okano), [0023] (“it is preferable that the hydrogen peroxide content of the sterilizing cleaner composition for hard surfaces of the present invention is 0.5 wt% or less, more preferably 0.3 wt% or less, and ***even more preferably 0.2 wt% or less.***”) (emphasis added).) A POSA would, therefore, have recognized that Okano’s Example 1 provides a 5-minute reaction time in order to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid.

130. Moreover, to the extent it is argued that 5 minutes may not be enough time for maximum conversion of the hydrogen peroxide triacetin into PAA under the specific alkaline-pH reaction conditions of Example 1, a POSA would have recognized that any additional conversion of the hydrogen peroxide and the triacetin into peracetic acid could be readily achieved, for example, by optimizing the pH of the alkaline solution (*e.g.*, by using a higher concentration of sodium hydroxide) added at step 4, which in turn will increase the reaction rate of the PAA generation, and then assessing the conditions under which the amount of residual hydrogen peroxide may be reduced even beyond that within Okano’s identified 5-minute reaction time. (*See, e.g.*, EX1010 (Copenhafer), [0054] (“The reaction between the hydrogen peroxide and acetic anhydride in the aqueous medium, to form dilute peracetic acid, increases in rate as the pH of the aqueous medium becomes more alkaline, generally providing higher yields of peracetic acid at shorter reaction

times.”).) In this regard, Okano expressly discloses that an acceptable range for the alkaline pH for the reaction of hydrogen peroxide with triacetin to form PAA is “a pH of 8 to 12.” (EX1005 (Okano), [0009], [0015], [0029], [0030], [0039], [0054].)

131. A POSA also would have routinely optimized other reaction parameters expected to affect the extent of the conversion of the hydrogen peroxide triacetin into peracetic acid in Okano’s Example 1, such as the reaction temperature. Thus, a POSA would have found it obvious to follow the teachings of Okano to maximize the conversion of the hydrogen peroxide and the triacetin into PAA.

132. Accordingly, claim 9 of the ’997 patent obvious in view of Okano.

9. Claim 10: “The method of claim 9, wherein the time to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid is about 30 seconds to about five minutes.”

133. As explained above regarding claim 9, Okano discloses the efficient generation of an organic peracid, notably of PAA, by minimizing the amount of unreacted residual hydrogen peroxide to “even more preferably 0.2 wt% or less.” (EX1005 (Okano), [0035], [0023].) Okano’s Example 1 teaches that the reaction mixture containing triacetin, hydrogen peroxide, water, and sodium hydroxide is “mixed and stirred for 5 minutes.” (EX1005 (Okano), [0057].) This disclosure of mixing the aqueous hydrogen peroxide triacetin solution “and stir[ring] for 5 minutes” falls within the claimed range of “about 30 seconds to about five minutes”

of claim 10 of the '997 patent.

134. A POSA would have understood and would have been motivated by Okano's stated desire to minimize the amount of unreacted residual hydrogen peroxide, coupled with the common general goal to optimize the conversion of reactants to products, to follow Okano's Example 1 and, if necessary, refine the reaction conditions to attain minimal residual hydrogen peroxide after the stated 5-minute reaction time, as described above with respect to claim 9. A POSA would have known that this could be readily achieved by increasing the rate of the alkali-catalyzed conversion of the hydrogen peroxide triacetin to PAA by raising the overall pH at step 4 of Example 1 through, for instance, adding a more concentrated solution of sodium hydroxide (*i.e.*, increasing further the 27% sodium hydroxide level). As noted for claim 9 above, Okano expressly discloses that an acceptable range for the alkaline pH for the reaction of hydrogen peroxide with triacetin to form PAA is "a pH of 8 to 12." (EX1005 (Okano), [0009], [0015], [0029], [0030], [0039], [0054].) Reaction time and rate are variables a POSA would have known to affect the extent of reaction. For instance, he or she would have easily been able to determine the reaction conditions to optimize the rate of conversion to PAA (thereby minimizing the amount of unreacted hydrogen peroxide per Okano's teaching) within 5 minutes of reaction time as set forth in Okano's Example 1, by determining the maximum conversion based on modification of the reaction mixture's pH within

Okano's identified pH range of 8 to 12. Thus, a POSA would have found claim 10 of the '997 patent is obvious in view of Okano.

10. Claim 11: “The method of claim 10, wherein [] the percent of triacetin that is converted into peracetic acid is about 40.9% to about 85.7%.”

135. The '997 patent discloses that “[w]hen triacetin is used as the acetyl precursor and *assuming all three acetyl groups are reacted*, about 40.9% to about 85.7% of the triacetin is converted into peracetic acid, and the percent of hydrogen peroxide remaining is about 0.078% to about 1.88%.” (EX1001 ('997 patent), 6:15-19 (emphasis added), 17:48-51 (similar).) Following this specific manner of determining “the percent of triacetin that is converted into peracetic acid” by “assuming all three acetyl groups are reacted,” Okano's Example 1 satisfies and, therefore, renders obvious claim 11 as explained further below. (See EX1001 ('997 patent), 18:54-56 (“The percent of the triacetin acetyl donor converted to PAA was calculated, assuming all three acetyl groups were available for perhydrolysis”).) To be clear, however, although I do not believe that “assuming all three acetyl groups are reacted,” as Patent Owner contends in the district court proceedings is the appropriate plain meaning interpretation of the claim term “the percent of triacetin is converted into peracetic acid,” I am applying Patent Owner's interpretation for the purposes of my opinions under claim 11 of the '997 patent in this Declaration.

136. As explained above, Okano generally discloses that its composition of

peracetic acid is generated by reaction of component (A), which is preferably triacetin, and component (B1), which is hydrogen peroxide, in water. In Example 1, Okano teaches that the reaction is comprised of 50 g of pure triacetin, 25 g of 60% hydrogen peroxide (which is equal to 15 g of hydrogen peroxide in the solution), 850 g of water, and 75 g of an alkaline aqueous solution containing sodium hydroxide. (EX1005 (Okano), [0057].) Okano further discloses that following the alkali-catalyzed reaction, the remaining hydrogen peroxide content was about 1500 ppm. (EX1005 (Okano), [0057].)

137. A POSA would have understood that the reaction solution after Okano's step 4 (and prior to the addition of the acidic quenching solution) totals 1000 g in weight. Considering that the bulk of the solution is made up of water, the reaction solution would have a volume of about 1 liter. A POSA would have further understood that a remainder of 1500 ppm of hydrogen peroxide in a 1 liter solution is about 1.5 g of hydrogen peroxide (amounting to about ~0.15 wt% hydrogen peroxide). Because the reaction began with 15 g of hydrogen peroxide and only about 1.5 g is left over, it follows that about 90%, or 13.5 g, of hydrogen peroxide has reacted.

138. Based on its molecular weight of approximately 34 g/mol, 13.5 g of hydrogen peroxide is about 0.40 moles. Likewise, 50 g of triacetin is 0.23 moles based on triacetin's molecular weight of 218 g/mol. Thus, "assuming all three acetyl

groups are reacted” as a measure for determining the conversion of triacetin into PAA, a POSA would have understood that 0.40 moles of hydrogen peroxide would have reacted with 0.23 moles of triacetin. Since triacetin has three ester groups and “assuming all three acetyl groups are reacted,” a POSA would have understood that three hydrogen peroxide molecules are needed to react with all three acetyl groups of the triacetin molecule. Dividing 0.40 moles of hydrogen peroxide by 3, a POSA would have concluded that 0.13 moles of triacetin would theoretically have been reacted (assuming all three acetyl groups per triacetin were involved in the reaction). Accordingly, the percent of conversion of triacetin into PAA “assuming all three acetyl groups are reacted” can be calculated as $100\% \times 0.13/0.23 = 57\%$. Thus, Okano’s Example 1 discloses a method wherein, based on the foregoing calculations and “assuming all three acetyl groups are reacted,” about 57% of all the triacetin’s acetyl groups were converted to PAA. Since such a 57% conversion “assuming all three acetyl groups are reacted” falls well within the claimed range of “about 40.9% to about 85.7%,” a POSA would have recognized that Okano’s Example 1 is a method wherein “the percent of triacetin converted into peracetic acid is in the range of “about 40.9% to about 85.7%” based on my foregoing analysis and “assuming all three acetyl groups are reacted.” Thus, claim 11 of the ’997 patent is obvious in view of Okano even under Patent Owner’s interpretation of this claim in the district court proceedings.

11. Claim 12: “The method of claim 6, wherein the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is about 4.2:3.8:1.”

139. In my opinion, Okano discloses to a POSA a method “wherein the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is about 4.2:3.8:1.”

140. Okano teaches a “sterilizing cleaner composition ... containing water and an organic peracid obtained by reacting (A) an ester of a polyhydric alcohol and an organic acid with (B1) hydrogen peroxide in a specific molar ratio in water at a pH of 8 to 12, and having a pH of 1 or more and less than 7 at 25° C.” (EX1005 (Okano), Abstract “[Resolution Means]”). Okano further discloses that the sterilization cleaner for generating peracetic acid “is prepared by setting the pH to 8 to 12, preferably to 9 to 11” through the use of an “an alkaline pH adjusting agent,” such as the preferred sodium hydroxide. (EX1005 (Okano), [0039], [0040] (“alkaline pH adjusting agents include alkali metal hydroxides such as sodium hydroxide”); *see also id.*, [0048].)

141. A POSA would have also understood that in Okano’s Example 1, after the “75 g of an alkaline aqueous solution containing 27% sodium hydroxide and 1.3% of organic phosphonic acid ... was poured in,” the reaction medium would have contained 0.51 moles of sodium hydroxide (*i.e.*, $75 \text{ g} \times 0.27 \div 40 \text{ g/mol}$) and 0.44 moles of hydrogen peroxide (*i.e.*, $25 \text{ g} \times 0.6 \div 34 \text{ g/mol}$). (EX1005 (Okano), [0057].)

A POSA would have known that hydrogen peroxide is a weak acid and, as such, would have expected the same amount of the strong base sodium hydroxide to overcome the acidity of the hydrogen peroxide and to convert the reaction medium to a pH range within Okano's desired alkaline pH values. (See EX1010 (Copenhafer), [0022] ("hydrogen peroxide is a weak acid").) Thus, a POSA would have looked to the relative amounts of sodium hydroxide to hydrogen peroxide in Okano's Example 1 as having exemplary reaction conditions for Okano's sterilizing cleaner to achieve the desired alkaline pH range, which in that example is at a NaOH:H₂O₂ molar ratio of 1.1:1. This molar/mole ratio of NaOH:H₂O₂ scales to a ratio of 4.2:3.8, which is the same as the claimed "mole ratio of the sodium hydroxide to the hydrogen peroxide" of "about 4.2:3.8[]" of claim 12 of the '997 patent.

142. In addition, Okano discloses that its composition of peracetic acid is "obtained by reacting component (A) and component (B1) in water in a molar [and hence mole] ratio of (A)/(B1) = 1/10 to 20/1[.]" (EX1005 (Okano), [0015]; *see also id.*, [0029], [0030].) Okano further discloses the "first composition for producing sterilizing cleaner," wherein the "molar ratio of the component (A) to the component (B1), [*i.e.*,] (A)/(B1), is preferably 1/10 to 20/1." (EX1005 (Okano), [0035].) This Okano's "preferabl[e] 1/10 to 20/1" range of triacetin to hydrogen peroxide molar/mole ratios corresponds to the inverse, hydrogen peroxide to triacetin,

“preferabl[e]” range of molar/mole ratios of 0.05:1 to 10:1.

143. A POSA would have recognized that Okano’s aforementioned “preferabl[e]” molar/mole ratios of 0.05:1 to 10:1 for H₂O₂:triacetin could be readily used within Okano’s Example 1 while maintaining the same relative molar ratio of NaOH:H₂O₂ within the example (*i.e.*, 4.2:3.8) to achieve the desired alkaline pH of 8 to 12 for the reaction medium. In other words, Okano discloses a method in accordance with its Example 1, wherein the molar ratio of NaOH:H₂O₂ is 4.2:3.8 and the disclosed molar ratios of H₂O₂:triacetin are within 0.05:1 to 10:1. This 0.05:1 to 10:1 range clearly encompasses the 3.8:1 mole ratio of hydrogen peroxide to triacetin taught by claim 12 of the ’997 patent. Likewise, even Okano’s narrower 0.1:1 to 10:1 (“more preferabl[e]”) and 0.1:1 to 5:1 (“even more preferabl[e]”) ranges of molar ratios of hydrogen peroxide to triacetin (EX1005 (Okano), [0035]) also encompass the claimed 3.8:1 mole ratio of hydrogen peroxide to triacetin.

144. Accordingly, Okano discloses to a POSA a method for generating PAA wherein the molar ratio of NaOH:H₂O₂:triacetin encompasses the claimed “mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is about 4.2:3.8:1.” Therefore, claim 12 of the ’997 patent is obvious in view of Okano.

12. Claim 13: “The method of claim 1, wherein steps (a) through (e) are performed on a continuous basis.”

145. In my opinion, Okano discloses and hence renders obvious generating

PAA by performing “steps (a) through (e)” of claim 1 of the ’997 patent “on a continuous basis.”

146. As explained above, Okano discloses generating peracetic acid in a way corresponding to steps (a) through (e) of claim 1. A POSA would have understood that, based on product demand, the steps outlined in Okano’s Example 1 could be performed on a continuous basis. According to Okano, large-scale sterilization of hard surfaces, such as in “food production plants, pharmaceutical production plants, hospitals, nursing homes, kitchens, bathrooms, and the like” is necessary to maintain a hygienic environment. (EX1005 (Okano), [0002].) Sterilization can and ideally should be incorporated into industrial processes and “steps such as supplying, mixing, and applying (painting, spraying, and the like) the active ingredient [such as PAA] are often automated.” (EX1005 (Okano), [0003].) A POSA would have understood from Okano’s disclosure that there would be high demand for the sterilizing cleaner comprising aqueous peracetic acid and that, to meet this demand, such peracetic acid solutions could be generated continuously (and also automated for greater efficiency).

147. For instance, a POSA would have been motivated to generate peracetic acid continuously for larger spaces, such as manufacturing and industrial plants, hospitals, nursing homes, and the like, as disclosed in Okano. And a POSA would have had a reasonable expectation of success in generating peracetic acid on a

continuous basis in view of Okano. Example 1 of Okano discloses the components and their quantities necessary to generate peracetic acid solutions using an alkali-catalyzed reaction of triacetin and hydrogen peroxide, which after 5 minutes is quenched with sulfuric acid for subsequent use as a sterilization solution. A POSA would have understood, and reasonably expected success in, continuously generating such peracetic acid solutions by following Okano's disclosures.

148. In other words, it would have been obvious to a POSA to tweak Okano's setup in order to perform steps (a) through (e) of claim 1 of the '997 patent on a continuous basis, thus making claim 13 of the '997 patent obvious in view of Okano.

13. Claim 14: "The method of claim 1, wherein steps (a) through (e) are performed on an intermittent basis."

149. In my opinion, Okano discloses and hence renders obvious a method, for generating peracetic acid "wherein steps (a) through (e) [of claim 1 of the '997 patent] are performed on an intermittent basis."

150. As described above regarding claim 1, Okano discloses a method whereby triacetin and hydrogen peroxide are mixed with water, and then sodium hydroxide is added to form an alkaline reaction medium for generating PAA. (EX1005 (Okano), [0057] (Example 1).)

151. A POSA would have understood that the generation of PAA according

to Okano's teachings could be performed on an intermittent basis (*i.e.*, at irregular intervals) in order to supply a desired quantity, and not more or less than that, of the PAA solution for use. Indeed, Okano discloses the testing of various PAA compositions in Table 1, including with respect to "Sterilizing cleaner composition (I)" and "Sterilizing cleaner composition (II)." (EX1005 (Okano), [0069]; *see also id.* at [0057] ("Preparation of Sterilization Cleaner Composition (I)") and [0058] ("Preparation of Sterilization Cleaner Composition (II)").) Okano further explains that "[e]valuation tests of detergency and sterilizing power were performed by the following methods using a test aqueous solution where the composition obtained using the sterilizing cleaner compositions (I) and (II) and the components shown in Tables 1 and 2 were diluted with water so as to achieve the organic peroxy acid concentrations in Tables 1 and 2." (EX1005 (Okano), [0060].) A POSA would have readily understood based on common sense that if the amount of the PAA composition made in a single batch was insufficient to perform all of the desired "Oil stain cleaning rate," "Protein stain cleaning rate," and "Sterilization power" testing of the composition (*e.g.*, "Sterilizing cleaner composition (I)" made according to the method of Okano's Example 1) (*see* EX1005 (Okano), [0069]), then the method of generating the PAA sterilizing cleaner composition could be performed on an intermittent basis according to need and demand for additional quantities of the sterilizing solution.

152. Accordingly, in my opinion, a POSA would have found obvious from the teachings of Okano a method for generating PAA that includes performing steps (a) through (e) of claim 1 of the '997 patent "on an intermittent basis."

B. Ground 2: Claims 1, 4, 5, and 13-14 are Obvious in View of the Combination of Okano (Ground 1) and Withenshaw

1. Motivation to combine and a reasonable expectation of success

153. In my opinion, a POSA would have been motivated to combine Okano and Withenshaw and able to do so successfully with no more than routine effort.

154. A POSA would have known that Okano and Withenshaw are both directed to the same rather narrow field of art, namely to generating and using peracetic acid aqueous solutions made from an acetyl precursor and hydrogen peroxide. (See EX1006 (Withenshaw), 1:1-3 ("This invention relates to peroxyacid delivery processes, in particular to processes in which a peroxyacid is formed by the reaction of *hydrogen peroxide* solution with a bleach activator."), 5:6-11 ("Activators generating peracids other than *peracetic acid* may be used but are not preferred. Specific activators, which are available for use in the invention, are tetraacetylenediamine (TAED), penta*acetyl* glucose (PAG), tetra*acetyl*glycolouril (TAGU), N-acetyl caprolactam, N-benzoyl caprolactam and tri*acetyl*ethanolamine. Of these TAED is preferred because it gives the most cost-effective release of *acetyl groups*: it releases two such groups per molecule"))

(emphasis added); EX1005 Okano, [0011] (“An ester between a polyhydric alcohol and an organic acid having a hydrocarbon group... of a component (A) *reacts with hydrogen peroxide to produce an organic peracid.*”), [0014] (“Specifically, the component (A) is preferably an ester of glycerin and an aliphatic monocarboxylic acid having 1 to 8 carbon atoms, and among these, *triacetin is preferable.*”) (emphases added).)

155. Indeed, the '997 patent specification describes “Withenshaw” as disclosing a “process for generating non-equilibrium solutions of PAA on site at the point-of-use[.]” (EX1001 ('997 patent), 4:28-30 (“WO 01/46519”).)

156. Okano and Withenshaw both disclose generating non-equilibrium peracetic acid solutions through the same alkali-catalyzed reaction of an acetyl precursor and hydrogen peroxide, including specifically the preferred use of sodium hydroxide to raise the pH to alkaline levels. (EX1006 (Withenshaw), 3:6-10 (“The present invention provides a peroxyacid delivery process for the continuous generation of peroxyacid from hydrogen peroxide solution and bleach activator characterised in that the pH of a mixture of hydrogen peroxide solution and bleach activator is adjusted by the addition or injection of an alkaline material selected from the group consisting of sodium hydroxide”), 4:14 (“In a preferred embodiment the alkaline material is sodium hydroxide.”); EX1005 (Okano), [0008] (“The present invention relates to a sterilizing cleaner composition for hard surfaces, containing

water and an organic peracid obtained by reacting (A) ... (B1) hydrogen peroxide (herein referred to as component (B1)) in water at a molar ratio of (A)/(B1) = 1/10 to 20/1 and at a pH of 8 to 12”), [0039]-[0040] (“[T]he sterilizing cleaner composition is prepared by setting the pH to 8 to 12, preferably to 9 to 11 (first step), ... In the first step, an alkaline pH adjusting agent is preferably used ... [e]xamples of alkaline pH adjusting agents include alkali metal hydroxides such as sodium hydroxide”), [0057] (Example 1).)

157. A POSA would also have known that peracids, including specifically peracetic acid, possess strong oxidizing potential for use in a variety of sterilizing and similar applications. (*See, e.g.*, EX1010 (Copenhafer), [0003] (PAA “is a well known chemical for its strong oxidizing potential”), [0005] (“Aqueous solutions of peracetic acid, at dilute concentrations below 5 wt% peracetic acid, are widely used in a variety of end use applications for their wide spectrum antimicrobial and biocidal properties, as a bactericide, fungicide, disinfectant and sterilant, and also for their bleaching properties.”); EX1008 (Tucker), Abstract (“Examples of suitable applications include disinfection of food processing equipment, disinfection of areas containing livestock, mold remediation, sterilization of medical instruments and direct disinfection of food surfaces, such as beef carcasses.”).) Indeed, both Withenshaw and Okano expressly describe and suggest overlapping, alternative, and complementary uses for the strongly oxidizing peracid solutions, including those of

PAA. For instance, Withenshaw notes that “[i]t has been proposed to use peroxyacid, especially peracetic acid, as a bleach or disinfectant.” (EX1006 (Withenshaw), 1:15-16.) Okano similarly teaches the benefits of peracetic acid solutions due to their strong disinfectant properties: “the sterilizing cleaner composition for hard surfaces of the present invention has a broad disinfecting spectrum and is highly effective not only against bacteria but also against fungi and spores, and is therefore useful for sterilizing and cleaning various hard surfaces.” (EX1005 (Okano), [0026].) Furthermore, Okano expressly discloses that peracid compositions can be used in “food production plants, pharmaceutical production plants, hospitals, nursing homes, kitchens, bathrooms, and the like.” (EX1005 (Okano), [0002].) Thus, a POSA would have readily recognized that the methods for generating peracetic acid solutions disclosed by both Withenshaw and Okano could be readily and interchangeably deployed for use in a variety of end-use applications.

158. The aims of the teaching of both Okano and Withenshaw are also the same: improved methods for efficiently generating peracetic acid aqueous solutions. (EX1005 (Okano), [0037] (“component (B1) and component (A) react efficiently, and taking into consideration the efficiency of organic peracid generation, bactericidal effect, formulation stability, and the like”); EX1006 (Withenshaw), 3:4-5 (“a safe, continuous process for [an] on site generation of peroxyacid with low

capital cost and short residence time”).) Considering that they are in the same rather narrow field of art and teach the use of chemically similar PAA-producing reactants (an acetyl precursor and hydrogen peroxide) using the same sodium hydroxide-based alkali-catalyzed reaction conditions for similar and overlapping applications, a POSA would have been motivated to combine the respective teachings of Okano and Withenshaw. Since both of these prior art references use old, standard, and well-established reagents and chemical methods, in my opinion, a POSA would have had a reasonable expectation of success in combining the respective teachings of Okano and Withenshaw.

159. Additionally, a POSA would also have been specifically motivated to combine Okano’s preferred triacetin-hydrogen peroxide method for efficiently generating peracetic acid solutions with Withenshaw’s disclosed “continuous peroxyacid generating system” to automate and scale-up Okano’s method into an industrial production process with desirable features. While Okano expressly acknowledges that “when a sterilization and cleaning process is incorporated into an industrial production process, steps such as supplying, mixing, and applying (painting, spraying, and the like) the active ingredient are often automated” (EX1005 (Okano), [0003]), it does not disclose a specific automated, industrially-applicable system for implementing the methods for generating PAA solutions from triacetin-hydrogen peroxide disclosed therein. A POSA, however, would have recognized

that the system taught by Withenshaw would be well-suited to implement, automate, and scale up Okano's methods for efficiently generating PAA. (*See* EX1006 (Withenshaw), 9:4-10 (batch-fed continuous generation of PAA, continuous input by metering pumps, and flow rate sensing for even "a more automated process" with variable flow rates).)

160. A POSA would also have understood that Withenshaw's system can provide not only the benefit of automation and increased production of Okano's PAA solutions, but also other benefits that would have further motivated the combination. For example, Withenshaw suggests that its system is desirable because it provides "a safe, continuous process for [an] on site generation of peroxyacid with low capital cost and short residence time." (EX1006 (Withenshaw), 3:4-5.) Thus, a POSA would have been motivated to use Withenshaw's system to achieve its expressly stated benefits—*i.e.*, a safe, low-cost, and efficient process. (*See* EX1006 (Withenshaw), 8:5-9 ("A further advantage of generating the peroxyacid continuously is that it may easily be controlled ... Another advantage of the continuous process is that it can easily be scaled up without using correspondingly larger mixing tanks, that may take up too much space to enable the equipment to be added into an existing manufacturing facility.") With respect to safety, a POSA would have recognized the benefit of Withenshaw's system as expressly disclosed therein: "because the system is then enclosed, exposure of an operator to peracetic

anion solution is reduced.” (EX1006 (Withenshaw), 7:16-17.)

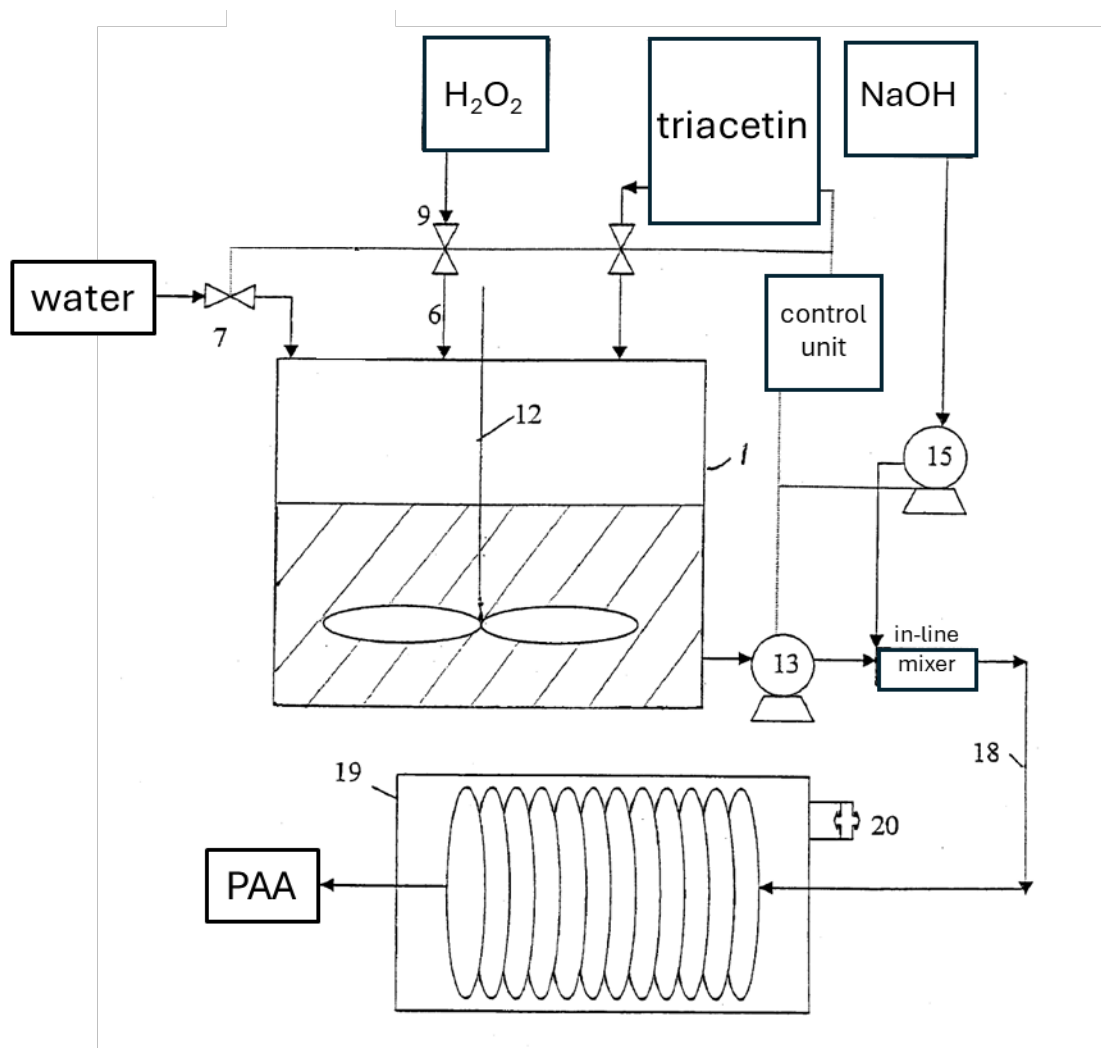
161. Another benefit touted by Withenshaw that would have further motivated the use of the system in combination with Okano’s triacetin-hydrogen peroxide method is the process adaptability and flexibility: “The process is adaptable to any location and the reaction pipe length can be adapted according to the distance from the dosing point, with bore and length of the reaction pipe and flow rate being conjointly selected to give the correct retention time.” (EX1006 (Withenshaw), 7:3-5.)

162. Because Withenshaw’s system was designed to implement a materially identical chemical process and is adaptable, implementing Okano’s preferred input of triacetin as the acetyl precursor instead of Withenshaw’s preferred TAED would have been well within the typical skill of, and routine effort by, a POSA. Indeed, he or she would have known that Okano’s triacetin is a liquid acetyl precursor and its use as a substitute for the solid, agglomerated TAED acetyl precursor of Withenshaw would improve and simplify the process for generating PAA. For instance, Withenshaw explains that “[u]se of TAED powder in a pre-reaction with hydrogen peroxide to form a bleaching solution for use in bleaching process is undesirable for a number of reasons,” including the difficulty of addition of the powder using a hopper, special equipment to control dust levels, and would not mix well due to having poor dispersing dissolution characteristics. (EX1006 (Withenshaw), 2:3-9.)

163. Withenshaw also notes the drawbacks of using “agglomerated” TAED, the drawbacks relating to the use of such binders with respect to solubility, undesirable side reactions, and scum formation. (EX1006 (Withenshaw), 2:10-3:3.) A POSA would have immediately recognized that these shortcomings and potential complications associated with the use of an agglomerated solid acetyl precursor (TAED) would not be present when using the liquid triacetin acetyl precursor taught by Okano. Indeed, a POSA would have understood that liquids can be much more easily used and controlled in the context of a scaled process than solids, including for the reasons expressly stated by Withenshaw. Accordingly, in my opinion, it would have been obvious to a POSA to use Okano’s preferred liquid triacetin acetyl precursor as a better and more well-suited acetyl precursor than Withenshaw’s agglomerated solid TAED.

164. Withenshaw’s system, such as in the exemplary Figure 1, uses standard tanks, pumps, valves, in-line mixer, and controls that would have been well known to a POSA and could have been readily implemented to use Okano’s preferred triacetin acetyl precursor. (*See, e.g.*, EX1006 (Withenshaw), 8:13-26, Figure 1.) A POSA would have found it obvious as part of this combination to make a simple substitution of Withenshaw’s “hopper 10” and “screw feeder 11” for supplying the solid agglomerated TAED acetyl precursor into mixing tank 1 with a tank akin to hydrogen peroxide tank 5, and control valve akin to control valve 9 along a flow

pipe between the triacetin tank and mixing tank 1 to supply Okano's liquid triacetin acetyl precursor into mixing tank 1. (See, e.g., EX1006 (Withenshaw), 8:14-26.) This straightforward combination of Okano's disclosures, particularly relating to Example 1, for generating PAA in water from the base-catalyzed reaction of triacetin and hydrogen peroxide within Withenshaw's disclosed system is schematically depicted as follows:



165. In sum, based on the foregoing, it is my opinion that a POSA would

have been motivated to combine the teachings of Okano and Withenshaw to generate PAA aqueous solutions that could be used in a variety of applications with a reasonable expectation of success in doing so.

2. Claim 1 is obvious in view of the combination of Okano and Withenshaw

166. In Ground 1 above, I explained how Okano discloses and hence renders obvious the method recited in claim 1 of the '997 patent. It is my opinion that Okano's disclosures (as set forth under Ground 1) implemented using Withenshaw's "continuous peroxyacid generating system" and teachings, also render claim 1 obvious.

a) 1[pre] "A method of generating a non-equilibrium solution of peracetic acid, comprising:"

167. To the extent the claim preamble is limiting, it is disclosed by both Okano and Withenshaw. I incorporate by reference my opinions expressed above under Ground 1 with respect to Okano for claim element 1[pre].

168. Withenshaw discloses that "[t]he present invention provides a peroxyacid delivery process for the continuous generation of peroxyacid from hydrogen peroxide solution and bleach activator characterised in that the pH of a mixture of hydrogen peroxide solution and bleach activator is adjusted by the addition or injection of an alkaline material selected from the group consisting of sodium hydroxide[.]" (EX1006 (Withenshaw), 3:6-10.) Withenshaw further

discloses that “[a]djustment of the pH to about 8 to about 9.5, *e.g.* by use of sufficient sodium hydroxide, is recommended for greater than 90% yield based on TAED.” (EX1006 (Withenshaw), 4:16-18.) From these disclosures, a POSA would have understood that Withenshaw also discloses the formation of an alkali-catalyzed non-equilibrium aqueous solution of peracetic acid.

169. Accordingly, both Okano and Withenshaw disclose “a method of generating a non-equilibrium solution of peracetic acid,” thus making this claim element of the ’997 patent obvious to a POSA.

b) 1[a] “a. providing water;”

170. As I set forth previously in Ground 1 (1[a]), Okano discloses a method for generating PAA that includes “providing water.” (*See* Ground 1, 1[a], above.) As noted above, Okano also discloses a method for generating “an organic peracid obtained by reacting component (A) and component (B1) *in water* in a molar ratio of (A)/(B1) = 1/10 to 20/1 and at a pH of 8 to 12[.]” (EX1005 (Okano), [0015] (emphasis added); *see also id.*, [0030].) Okano’s Example 1 further discloses the reaction of triacetin (as component (A)) and hydrogen peroxide (B1) by adding and mixing them *into 850 g of water*. (EX1005 (Okano), [0057] (emphasis added).) Thus, Okano discloses the “providing water” step, and, as previously discussed in Ground 1, to mix and/or react triacetin (A) and hydrogen peroxide (B1) in water would necessarily involve providing the water.

171. Withenshaw also discloses the step of “providing water” as part of a method for generating aqueous PAA solutions. Additionally, Withenshaw discloses that “Figure 1 shows a batch make-up tank 1. The tank is fed with water along delivery pipe 2.” (EX1006 (Withenshaw), 8:14-15.) Withenshaw further discloses that “[t]he continuous process operates as follows: the control unit 17 opens valve 7 to allow approximately 100 kg of water to enter the batch make-up tank 1 along supply pipe 2.” (EX1006 (Withenshaw), 8:27-29.) Thus, Withenshaw also discloses the step of “providing water.”

172. Accordingly, both Okano and Withenshaw disclose the step of “providing water” in a method for generating PAA, thereby satisfying claim element 1[a] of the ’997 patent.

c) 1[b] “b. introducing triacetin and aqueous hydrogen peroxide to the water;”

173. As described above in Ground 1 with respect to claim element 1[b], Okano discloses “introducing triacetin and aqueous hydrogen peroxide to the water,” such as disclosed in Example 1. (EX1005 (Okano), [0057]). Thus, Okano discloses introducing triacetin and aqueous hydrogen peroxide to the water” as part of generating PAA. (See Ground 1, 1[b], above.) As further described previously, Okano’s exemplary hydrogen peroxide-triacetin method of Example 1 discloses adding and mixing triacetin and hydrogen peroxide with the water. (See Ground 1,

1[b], above.)

174. Withenshaw similarly discloses the addition of an acetyl precursor (preferably TAED) and hydrogen peroxide to water in the batch make-up tank 1. (EX1006 (Withenshaw), 8:14-19.) Specifically, it discloses: “Figure 1 shows a batch make-up tank 1. The tank is fed with water along delivery pipe 2. Sequestrant is dosed from tank 3 along sequestrant supply pipe 4. Hydrogen peroxide is dosed from tank 5 along peroxide supply pipe 6. Valves 7, 8 and 9 control the water, sequestrant and peroxide supplies respectively. Agglomerated TAED is held in a hopper 10 and fed to the tank 1 via a screw feeder 11.” (EX1006 (Withenshaw), 8:14-18.) Accordingly, Withenshaw discloses that the acetyl precursor and hydrogen peroxide are introduced into the water. A POSA would have found it obvious that implementing Okano’s method for generating PAA using triacetin and hydrogen peroxide would also follow the same order of steps, in that the triacetin and the aqueous hydrogen peroxide would be added into the water in Withenshaw’s batch make-up tank 1.

175. Withenshaw further discloses that “[t]he continuous process operates as follows: the control unit 17 opens valve 7 to allow approximately 100 kg of water to enter the batch make-up tank 1 along supply pipe 2. At the same time 0.2 kg of sequestrant is dosed along pipe 4 by opening valve 8 and agglomerated TAED also enters tank 1 from hopper 10 by operation of the screw feeder 11. This takes about

1 minute. Throughout the fill cycle the agitator 12 is in continuous operation. Towards the end of the cycle the hydrogen peroxide is dosed along line 6 when the controller 17 opens valve 9. At the end of this fill cycle the level in tank 1 is at its maximum.” (EX1006 (Withenshaw), 8:27-9:5.) In this part of its specification, Withenshaw discloses that “[t]owards the end of the cycle the hydrogen peroxide is dosed” into the batch make-up tank, indicating that the hydrogen peroxide is added to the provided water.

176. Although Withenshaw suggests that the sequestrant and TAED can be added “at the same time” as the water, a POSA would have understood that the TAED is “agglomerated” and the addition of the sequestrant is included in Withenshaw’s process because the acetyl precursor (TAED) is in a solid, agglomerated form. The method of Okano using liquid triacetin as the acetyl precursor, however, would not require such a sequestrant and would not have to deal with for the agglomerated nature of the TAED since both the aqueous hydrogen peroxide and the triacetin are liquids. Accordingly, a POSA would have found it obvious to “dose” Okano’s liquid triacetin acetyl precursor into the batch make-up tank in a manner similar to how Withenshaw discloses for the TAED in relation to the aqueous hydrogen peroxide. In other words, the batch make-up tank would have the water added first, then introducing the triacetin, and then “[t]owards the end of the cycle the hydrogen peroxide is dosed.” (EX1006 (Withenshaw), 9:3-5.) Thus,

a POSA would have found that the combination of Okano and Withenshaw discloses introducing triacetin and aqueous hydrogen peroxide to the water.

177. Accordingly, in my opinion, Okano and Withenshaw, as well as the Okano and Withenshaw combination, disclose and hence render obvious the step of “introducing triacetin and aqueous hydrogen peroxide to the water,” as recited in claim element 1[b] of the ’997 patent and that this claimed step necessarily occurs *after* the step of “providing [the] water.”

d) 1[c] “c. mixing the triacetin and the aqueous hydrogen peroxide with the water to form a mixture;”

178. As described above in Ground 1 regarding claim element 1[c] Okano discloses “mixing the hydrogen peroxide-triacetin solution and the water to form a mixture.” For instance, Okano’s Example 1 for generating PAA discloses that the triacetin and hydrogen peroxide “were *mixed* with 850 g of ion exchanged water.” (EX1005 (Okano), [0057] (emphasis added).)

179. Withenshaw discloses that during the fill cycle, in which the water, acetyl precursor, and (thereafter) aqueous hydrogen peroxide is dosed into the batch make-up tank 1, “the agitator 12 is in continuous operation.” (EX1006 (Withenshaw), 9:2-3.) A POSA would have understood that agitator 12, as shown in Fig. 1, is used to mix the components dosed into batch make-up tank 1. (EX1006 (Withenshaw), 8:18-19 (“The contents of tank 1 are ... mixed using an agitator 12.”).)

180. Thus, in my opinion, the combination of Okano and Withenshaw, individually and in combination, discloses and hence renders obvious to a POSA the “mixing the hydrogen peroxide-triacetin solution and the water to form a mixture” claim element of the ’997 patent, *i.e.*, that the triacetin and the aqueous hydrogen peroxide are mixed with the water to form a “mixture” within Withenshaw’s batch make-up tank 1.

e) 1[d] “d. adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture; and”

181. Both Okano and Withenshaw disclose the generation of PAA through the addition of an alkaline material to the aqueous solution containing the acetyl precursor (*e.g.*, triacetin), hydrogen peroxide, and water.

182. As demonstrated previously, Okano discloses this claim limitation of the ’997 patent. (*See* Ground 1, 1[d], above.) Okano states that the sterilizing non-equilibrium aqueous solution of peracetic acid is prepared “by setting the pH to 8 to 12, preferably to 9 to 11,” where “an alkaline pH adjusting agent is preferably used[.]” (EX1005 (Okano), [0039].) Okano also discloses examples of alkaline pH adjusting agents, expressly including sodium hydroxide. (EX1005 (Okano), [0040] (“Examples of alkaline pH adjusting agents include alkali metal hydroxides such as sodium hydroxide... .”), [0048] (“The component (A) and the component (B1) react under alkaline conditions (water temperature 5 to 50 [°C] is suitable) in water to

generate an organic peroxy acid, and therefore, a component that gives such a pH may be used as the component (C). Specifically, ***examples include alkali metal hydroxides such as sodium hydroxide, potassium hydroxide, calcium hydroxide, and barium hydroxide, alkaline earth metal hydroxides***) (emphasis added.)

183. Withenshaw discloses a “peroxyacid delivery process for the continuous generation of peroxyacid,” wherein the acetyl precursor, hydrogen peroxide, and water are “mixed together in a tank (1), the pH of the mixture is adjusted by the addition or injection of an alkaline material (16) selected from the group consisting of sodium hydroxide, potassium hydroxide and magnesium oxide under vigorous mixing conditions such as are provided by an in-line mixer (14)” (EX1006 (Withenshaw), Abstract; *see also id.*, 3:6-11 (“The present invention provides a peroxyacid delivery process for the continuous generation of peroxyacid from hydrogen peroxide solution and bleach activator characterised in that the pH of a mixture of hydrogen peroxide solution and bleach activator is adjusted by ***the addition or injection of an alkaline material selected from the group consisting of sodium hydroxide, potassium hydroxide and magnesium oxide*** under vigorous mixing conditions provided by an in-line mixer”) (emphasis added), 4:14-18 (“In a preferred embodiment the alkaline material is sodium hydroxide.... Adjustment of the pH to about 8 to about 9.5, *e.g.* by use of sufficient sodium hydroxide, is recommended”).) As Withenshaw further teaches with respect to the disclosed

system in Figure 1, “[t]he outlet from tank 1 is fed by pump 13 to in-line mixer 14. The in-line mixer is also fed through pump 15 with caustic soda solution from tank 16.” (EX1006 (Withenshaw), 8:18-21.) Thus, Withenshaw discloses that the alkali metal hydroxide (*e.g.*, sodium hydroxide) is added to and mixed with the acetyl precursor, hydrogen peroxide, and water mixture from tank 1 as a downstream step associated with in-line mixer 14.

184. Accordingly, in my opinion, the Okano and Withenshaw combination discloses and hence render obvious a method for generating PAA that includes the “adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture” claim element of the ’997 patent, and that this claimed step occurs *after* the step of mixing the hydrogen peroxide, triacetin, and water to form a mixture.

f) 1[e] “e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.”

185. Both Okano and Withenshaw, individually and in combination, disclose and hence render this claim limitation of the ’997 patent obvious.

186. As previously explained in Ground 1 regarding claim element 1[e], Okano discloses the formation of a reaction medium comprising a non-equilibrium solution of peracetic acid by reacting triacetin with aqueous hydrogen peroxide when the pH is raised to 8 to 12 upon addition of an alkali metal hydroxide such as sodium hydroxide. (*See* Ground 1, 1[e], above; *see also, e.g.*, EX1005 (Okano), [0015]

(“sterilizing cleaner composition for hard surfaces of the present invention contains water and an organic peracid *obtained by reacting component (A) and component (B1) in water* in a molar ratio of $(A)/(B1) = 1/10$ to $20/1$ and *at a pH of 8 to 12*” (emphases added)), [0048] (“The component (A) and the component (B1) *react under alkaline conditions* (water temperature 5 to 50 [°C] is suitable) in water to generate an organic peroxy acid, and therefore, a component that gives such a pH may be used as the component (C). Specifically, *examples include alkali metal hydroxides such as sodium hydroxide, potassium hydroxide, calcium hydroxide, and barium hydroxide, alkaline earth metal hydroxides*”) (emphases added).)

187. Withenshaw likewise discloses the formation of a reaction medium to generate a non-equilibrium aqueous solution of peracetic acid upon the addition of an alkaline material to raise the pH and to initiate the conversion of an acetyl precursor and hydrogen peroxide to peracetic acid: “the continuous generation of peroxyacid from hydrogen peroxide solution and bleach activator characterised in that the pH of a mixture of hydrogen peroxide solution and bleach activator is adjusted by the addition or injection of an alkaline material selected from the group consisting of sodium hydroxide, potassium hydroxide and magnesium oxide under vigorous mixing conditions provided by an in-line mixer[.]” (EX1006 (Withenshaw), 3:6-11; *see also id.*, 3:29-4:2 (“In-line mixers can enable the injection of the alkaline material in an essentially enclosed part of the system under continuous

flow conditions between the supply of mixed hydrogen peroxide and activator and a continuous supply outlet for the peroxyacid containing product.”), 9:24-26 (“The in-line mixer 14 creates turbulent flow, causing intimate mixing of the sodium hydroxide and the TAED/peroxide mixture which leads to ***the reaction progressing rapidly ...***” (emphasis added)), Abstract (“Preferably the output of mixer (14) is fed through a pipe (18), which may be coiled through a cooling tank (19) for heat dissipation, to provide a residence time of 4 to 25 minutes for completion of ***the reaction*** without degradation of the product” (emphasis added)), 12:17-19 (Claim “4. A peroxyacid delivery process according to any preceding claim in which ***after said addition or injection of alkaline material the reaction mixture*** is pumped along a pipe with a residence time of between 4 and 25 min.”) (emphasis added).) Indeed, the ’997 patent specification acknowledges that Withenshaw discloses a “process for ***generating non-equilibrium solutions of PAA*** on site at the point-of-use[.]” (EX1001 (’997 patent), 4:28-46 (“WO 01/46519 A1”) (emphasis added).)

188. In my opinion, therefore, because all elements of claim 1 of the ’997 patent were disclosed to a POSA by the Okano and Withenshaw combination, that patent claim is invalid for obviousness.

3. Claim 4: “The method of claim 1, wherein the provided water is an aqueous stream.”

189. Okano and Withenshaw both disclose the “provided water is aqueous

stream” claim element of the ’997 patent.

190. As previously described regarding claim 4 of the ’997 patent, a POSA would have found that Okano discloses that “the provided water is an aqueous stream.” (*See* Ground 1, 1[e], above.)

191. Withenshaw also discloses providing water as an aqueous stream, particularly in connection with the system depicted in Figure 1. (EX1006 (Withenshaw), 8:13 (“Figure 1 is a schematic of a continuous peroxyacid generating system.”).) In part, Withenshaw describes the operation of the system in Figure 1 as providing water in the form of an aqueous stream from a pipe (2) to the batch make-up tank (1): “Figure 1 shows a batch make-up tank 1. The tank is *fed with water along delivery pipe 2*... . The continuous process operates as follows: *the control unit 17 opens valve 7 to allow approximately 100 kg of water to enter the batch make-up tank 1 along supply pipe 2.*” (EX1006 (Withenshaw), 8:14-29 (emphasis added).)

192. Thus, in my opinion, the Okano and Withenshaw combination renders claim 4 of the ’997 patent obvious to a POSA.

4. Claim 5: “The method of claim 1, wherein the provided water is contained in a mixing tank or other vessel.”

193. Okano and Withenshaw both disclose a method of generating peracetic acid “wherein the provided water is contained in a mixing tank or other vessel.” As

previously explained in Ground 1, Okano discloses claim 5 of the '997 patent. The method and system taught in Withenshaw also discloses that the provided water is contained in a mixing tank or other vessel. Withenshaw discloses that the batch make-up tank is fed with water along delivery pipe 2. (EX1006 (Withenshaw), 8:14-15.) Withenshaw's batch make-up tank is a mixing tank. (EX1006 (Withenshaw), 8:18-19 ("The contents of tank 1 are ... mixed using an agitator 12.")) Thus, either Withenshaw's batch make-up tank (a "mixing tank") or delivery pipe 2 ("other vessel") contains the water that is "provided." (*See also* EX1006 (Withenshaw), 8:27-9:5 ("The continuous process operates as follows: the control unit 17 opens valve 7 to allow approximately 100 kg of water to enter the batch make-up tank 1 along supply pipe 2 ... This takes about 1 minute. Throughout the fill cycle the agitator 12 is in continuous operation. Towards the end of the cycle the hydrogen peroxide is dosed along line 6 when the controller 17 opens valve 9. At the end of this fill cycle the level in tank 1 is at its maximum."))

194. Thus, the Okano and Withenshaw combination discloses and hence renders obvious claim 5 of the '997 patent.

5. Claim 13: "The method of claim 1, wherein steps (a) through (e) are performed on a continuous basis."

195. The Okano and Withenshaw combination discloses that "steps (a) through (e) are performed on a continuous basis." As previously explained

regarding claim 13 in Ground 1, a POSA would have found it obvious that Okano's method for generating PAA is "performed on a continuous basis."

196. The implementation of Okano's method for generating PAA from the preferred triacetin and hydrogen peroxide in combination with Withenshaw further discloses performing steps (a) through (e) on a continuous basis. Withenshaw explains that the disclosed "peroxyacid delivery process [is] for the continuous generation of peroxyacid[.]" (EX1006 (Withenshaw), Abstract.) In addition, "Figure 1 is a schematic of a continuous peroxyacid generating system." (EX1006 (Withenshaw), 8:13.) Withenshaw further details how the system of Figure 1 implements a continuous batch-fed or ongoing automated continuous process utilizing metering pumps and/or using control sensors:

The *continuous process* operates as follows ... Pump 13 empties tank 1 *continuously* and at a defined lower level of liquid in tank 1, or a defined period of time, the fill cycle starts again. Alternatively in a modification *continuous metering pumps deliver all the components on a continuous basis*. In a more automated process for variable flow rates, the flow rate is sensed, for example near the output 21, and is used to control *the continuous metering pumps*.

The homogeneous mixture or suspension of TAED, hydrogen peroxide, water and sequestrant is *continuously dosed* by pump 13

through the in-line mixer 14 where sodium hydroxide *is also dosed continuously* via pump 15 in sufficient quantity to give the required pH at the end of the reaction, *e.g.* at or near the end 21 of pipe 18. Once an empirical relationship has been determined the controller 17 controls the sodium hydroxide delivery by controlling pump 15 according to the setting of pump 13 which in turn is set by the overall flow requirement. In an alternative process, pH is determined, for example at or near an end 21 of pipe 18, and is used to control pump 15.

(EX1006 (Withenshaw), 8:14-9:19 (emphases added).)

197. In my opinion, it would have been obvious to a POSA to combine Okano's method for performing steps (a) through (e) of claim 1 using Withenshaw's disclosed continuous manufacturing system. Thus, claim 14 of the '997 patent is obvious in view of the Okano and Withenshaw combination.

6. Claim 14: "The method of claim 1, wherein steps (a) through (e) are performed on an intermittent basis."

198. In my opinion, the Okano and Withenshaw combination discloses and hence renders obvious a method for generating peracetic acid "wherein steps (a) through (e) [of claim 1 of the '997 patent] are performed on an intermittent basis."

199. As previously described regarding claim 14 under Ground 1, Okano's disclosures alone render claim 14 obvious. Withenshaw's ideally suited system for

implementing Okano's PAA generating methods also renders this claim obvious.

200. Withenshaw discloses that the exemplary system can be implemented by dosing the acetyl precursor and hydrogen peroxide (*i.e.*, Okano's preferred hydrogen peroxide-triacetin solution as a "first composition") into water within tank 1 intermittently in conjunction with fill cycles: "At the end of this fill cycle the level in tank 1 is at its maximum. Pump 13 empties tank 1 continuously and at a defined lower level of liquid in tank 1 the fill cycle starts again." (EX1006 (Withenshaw), 9:4-7.) That is, Withenshaw discloses that the system can be operated on an intermittent basis by dosing tank 1 with the hydrogen peroxide and acetyl precursor components to a given level (or amount) and then further processing those reagents into the downstream steps involving the in-line mixer on an as-needed basis.

201. Accordingly, in my opinion, a POSA would have understood the Okano and Withenshaw combination disclosed and taught a method for generating PAA that includes performing steps (a) through (e) of claim 1 "on an intermittent basis."

C. Ground 3: Claim 8 is Obvious Under Okano in Combination with Oringer

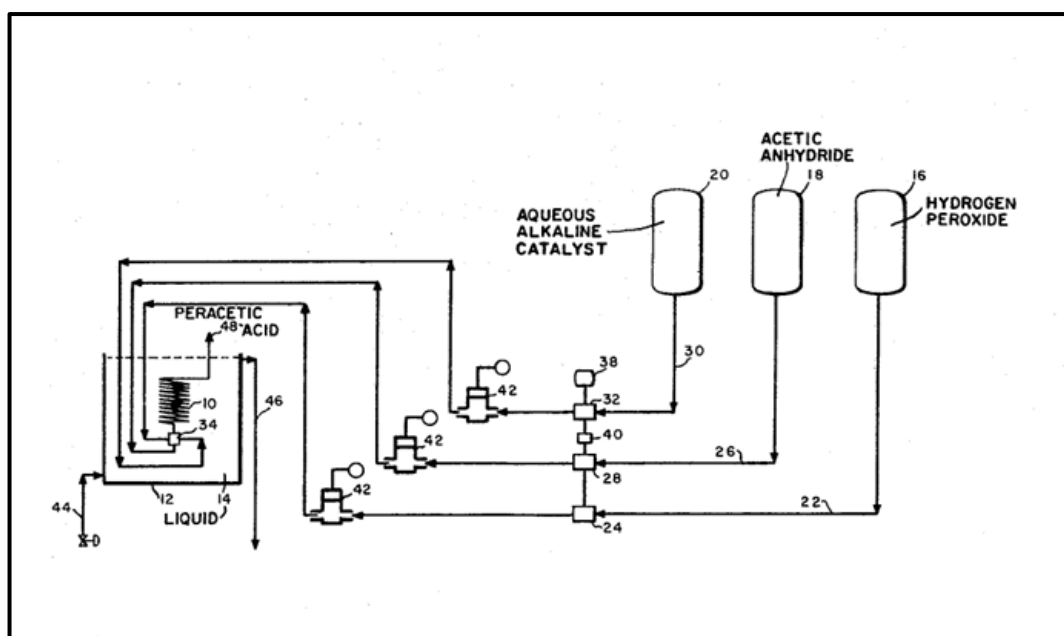
1. Motivation to combine and a reasonable expectation of success

202. Both Okano and Oringer are directed to methods for efficiently producing peracids, including specifically peracetic acid. (*See, e.g.*, EX1005 (Okano), [0006], [0057] (Example 1: reacting triacetin and hydrogen peroxide to

make peracetic acid), [0059] (method for determining the “peracetic acid concentration”); EX1007 (Oringer), Title (“Manufacture of Peracetic Acid”).) Just like Okano, Oringer discloses a method of reacting hydrogen peroxide with an acetyl precursor under alkaline conditions formed through addition of an alkali metal hydroxide, such as sodium hydroxide. (*See, e.g.*, EX1007 (Oringer), Abstract (1:11-21), 4:49-51 (“An alkaline catalyst is used in this reaction to promote conversion of the hydrogen peroxide and acetic anhydride to peracetic acid.”), 4:61-64 (“The alkaline agents which are used as catalysts likewise are those which are compatible with active oxygen as hydrogen peroxide and peracetic acid, and include sodium hydroxide...”).) Thus, Okano and Oringer are directed to the same rather narrow art of methods for making aqueous solutions containing peracetic acid; therefore, in my opinion, a POSA would have been motivated to combine these two prior art references and expected to successfully achieve that.

203. Oringer discloses the use of a tubular reactor to combine and mix the hydrogen peroxide, acetyl precursor, and an alkaline catalyst. (EX1007 (Oringer), Abstract (1:11-21), 2:35-56.) Specifically, it discloses “[a] method for the production of an aqueous peracetic acid solution by the reaction of hydrogen peroxide with acetic anhydride [acetyl precursor] in the presence of an alkaline catalyst comprising continuously introducing the reactants into a tubular reaction zone at a rate to produce a turbulent flow” (EX1007 (Oringer), Abstract (1:11-

21).) The following patent's figure "shows the apparatus of this invention which is particularly useful in carrying out the herein process" (EX1007 (Oringer), 5:21-24):



(EX1007 (Oringer), 5:21-67, Figure.)

204. With respect to the foregoing reactor design diagram, Oringer discloses that reactants are fed into a tubular coiled reaction zone 10 from three feed tanks: tank 16 containing hydrogen peroxide; tank 18 containing the acetyl precursor acetic anhydride; and tank 20 containing the aqueous alkaline catalyst. (EX1007, (Oringer), 5:25-32.) The reactants are then fed into mixer 34 "where they are blended for passage into reaction zone 10" by metering pumps that maintain a predetermined ratio of feed of the reactants. (EX1007 (Oringer), 5:33-39.) Oringer further discloses that the system has a "magnetic clutch 40" (*i.e.*, a control valve) to permit the aqueous hydrogen peroxide feed to be introduced alone into the "reactor

coil 10” in order to “flush[] the system” during “start-up and shut-down of the apparatus[.]” (EX1007 (Oringer), 5:41-49.)

205. A POSA would have recognized Oringer’s process to be well suited for generating PAA in combination with Okano’s methods teaching the use of triacetin, hydrogen peroxide, and an alkaline catalyst as a feed streams to be introduced into and mixed with water to generate an aqueous peracetic acid solution. A POSA would have been able to modify Oringer’s specifically described apparatus using only common skill and routine effort to implement Okano’s method. A POSA would have made such a modification to Oringer’s apparatus by: (1) providing a feedstock of Okano’s triacetin as the acetyl precursor instead of Oringer’s acetic anhydride within tank 18 and (2) adding a water input to “mixer 34” to achieve Okano’s teaching in Example 1 that the triacetin and aqueous hydrogen peroxide “were mixed” with the water, such as using the control valve with a water feed to enable “flushing the system” of any of the reagents during start-up and shut-down of the system.

2. Claim 8: “The method of claim 1, wherein step (d) is performed simultaneously with step (b).”

206. As described above in Ground 1, the method of claim 1 of the ’997 patent is disclosed by Okano. I incorporate those Ground 1 opinions regarding claim 1 here because claim 8 directly depends from claim 1.

207. As previously noted, I do not believe that the recited language of claim 8 of the '997 patent requiring that “step (d) is performed simultaneously with step (b)” can be reasonably reconciled with the express language of claim 1 requiring the steps to be performed in order *i.e.*, sequentially as listed. However, I understand from counsel that Patent Owner contends that claim 1 of the '997 patent does not require any particular order of steps and that claim 8 can be satisfied despite being, in my opinion, inconsistent with claim 1. Therefore, my opinions with respect to claim 8 under Ground 3 apply Patent Owner’s interpretation of claims 1 and 8 even though I disagree with that interpretation.

208. In my opinion, under Patent Owner’s interpretation, claim 8 is obvious in view of the combination of Okano’s method for generating PAA using Oringer’s apparatus for the manufacture of PAA. Oringer’s method depicts an apparatus wherein each of the reactant feed streams for generating PAA are simultaneously introduced into mixer 34. (EX1007 (Oringer), Figure, 5:25-48.) Implementing Okano’s method in a similar manner—*i.e.*, by simultaneously mixing the hydrogen peroxide-triacetin solution and the alkaline catalyst (*e.g.*, sodium hydroxide) into the water feed stream—would form a reaction medium generating PAA according to the method and apparatus taught in Oringer.

209. Therefore, under Patent Owner’s interpretation of claim 1, dependent claim 8 of the '997 patent would have been obvious to a POSA in view of the Okano

and Oringer combination.

XI. RESERVATION OF RIGHTS

210. I reserve the right to supplement my opinions expressed herein in the future to respond to any arguments that Patent Owner or its expert(s) may raise and to consider new information as it becomes available to me.

XII. ATTESTATION

I declare that all statements made herein of my own knowledge are true to the best of my knowledge and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: 8/30/2025



Alexander M. Klibanov, Ph.D.